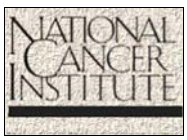

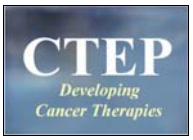

CANCER THERAPY EVALUATION PROGRAM, NATIONAL CANCER INSTITUTE

Clinical Data Update System (CDUS) Report Writer

CDUS REPORT WRITER VERSION 4.0, EQW RELEASE 1.4.0 — JULY 2, 2007

APPLICATION GUIDE

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PRODUCED BY CAPITAL TECHNOLOGY INFORMATION SERVICES, INC.

The Clinical Data Update System (CDUS) Report Writer Application Guide was prepared for:

Cancer Therapy Evaluation Program (CTEP)

Division of Cancer Treatment and Diagnosis (DCTD)

National Cancer Institute (NCI)

National Institutes of Health (NIH)

By:

Capital Technology Information Services, Inc.

One Research Court, Suite 200

Rockville, Maryland 20850–3236

Tel: 301-948-3033

Fax: 301-948-2242

Home Page: http://www.ctisinc.com

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The date on the cover of this application guide reflects the document release date, which may differ from the software release date.

Information within this application guide is current as of the date of publication. Software changes and enhancements incorporated into the system after the publication date will be reflected in future releases of the guide.

This application guide contains sample queries and screen examples taken from the CTEP-ESYS development database. If you are using the CTEP-ESYS production database, your query and screen data may differ from that depicted in this guide.

Contents

Introduction

Capital Technology Information Services, Inc. (CTIS) developed the Clinical Data Update System (CDUS) for the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI). The CDUS is the primary source of clinical trial data for the Division of Cancer Treatment and Diagnosis (DCTD) and the Division of Cancer Prevention (DCP).

The CDUS Report Writer enables you to view and generate reports about various aspects of the clinical trial process. The Report Writer is a component of the Enterprise Query Wizard (EQW), which is a tool that is used to access information in the CTEP Enterprise System database. It is designed to allow you to access and arrange data to meet your needs.

CTEP and CTIS welcome your comments and suggestions and will make every effort to incorporate them into our procedures, software, and documentation.

About This Guide

The *Report Writer Application Guide* provides detailed descriptions of the features that are used to generate CDUS reports. It also provides instructions for running each report. This *Application Guide* is subdivided into the following topics:

Each topic describes how to run a report or group of reports. It also provides business rules and definitions for each field in the report.

Note: The topics may be read in any sequence. You do not need to read all of the topics to understand how to operate the CDUS Report Writer.

Conventions Used in This Guide

In this guide, the commands, menus, text box names, dialog box titles, and the options that you need to activate appear in **bold** text. Other references or information that you need to enter appears in *Italics*.

The term **click** indicates that you need to move the mouse to an item and press the left button once. **Enter** indicates that you need to type information in a location. **Select** indicates that you need to highlight an item or option. The term **Choose** indicates that you need to activate a command.

System Requirements

The following is the minimum equipment configuration needed:

- An IBM®-compatible personal computer with an 80486sx, 80486, or higher processor (80486/20 or higher recommended).
- Microsoft® Windows 95 or 98.
- A hard disk with 100 megabytes (MB) of free space.
- 128 MB or higher of random-access memory (RAM).
- A Microsoft® mouse or other compatible pointing device.
- An EGA, VGA, or compatible display (VGA or higher recommended).

Contact the CTEP Help Desk at ctephelp@ctep.nci.nih.gov to obtain user accounts.

Further Information

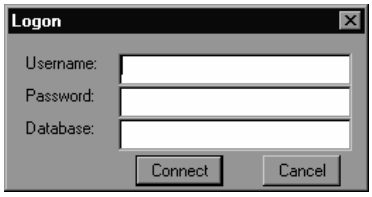
For further information, please contact the CTEP Help Desk at ctephelp@ctisinc.com.

Refer to the following resources for additional information:

- NCI CTEP Home Page: http://ctep.cancer.gov
- NCI CTEP Enterprise System (CTEP-ESYS) User's Guide
- NCI CTEP Enterprise Query Wizard (EQW) User's Guide

Using the CDUS Report Writer

The CDUS Report Writer is part of the Enterprise Query Wizard (EQW). EQW enables you to access information in the CTEP Enterprise System database with one interface. It is designed to allow you to retrieve and arrange data from all of the applications in the Enterprise System to meet your needs. Do the following to log on to the EQW:



1. Double-click the Enterprise Control Panel icon on your desktop. The **Logon** dialog box opens.
2. Enter your user name in the **Username** field and move to the **Password** field.
3. Enter your password in the **Password** field.
4. Enter your database location (CTEPESYSPROD) in the **Database** field.
5. Click **Connect**.

Figure 1 The CTEP Enterprise System Front Panel

6. Click **EQW** when the CTEP Enterprise System Front Panel (Figure 1) opens.

The Enterprise Query Wizard screen opens, as shown in Figure 2.

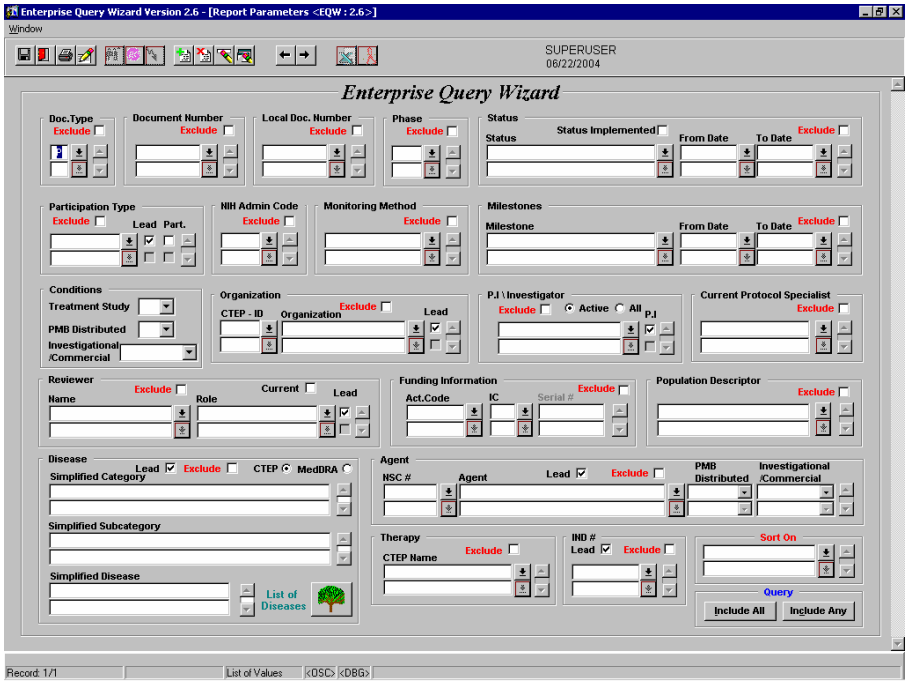


Figure 2 - Enterprise Query Wizard Screen

After you access the Enterprise Query Wizard, you need to run a query to open the CDUS Report Writer. The criteria you enter here will not affect the report you run, however. You will enter a new set of parameters to run the report. Complete the following steps to perform a basic query.

1. Click the **Doc. Type** drop-down list button. Select **Protocol** from **the List of Document Type(s)**.
2. Click the **Document Number** drop-down list button and select a document number.
3. Click **Include All** or **Include Any**.

Select **Include All** to search for documents that contain all of the information that you entered. Select **Include Any** to search for documents that contain any of the information that you entered. **Include All** will generally produce a more manageable list of items that exactly match the query information you entered on the screen.

The Query Results screen displays a list of documents that contain the criteria you selected. Use the scroll bars to review additional matches. Figure 3 is an example of a query result.

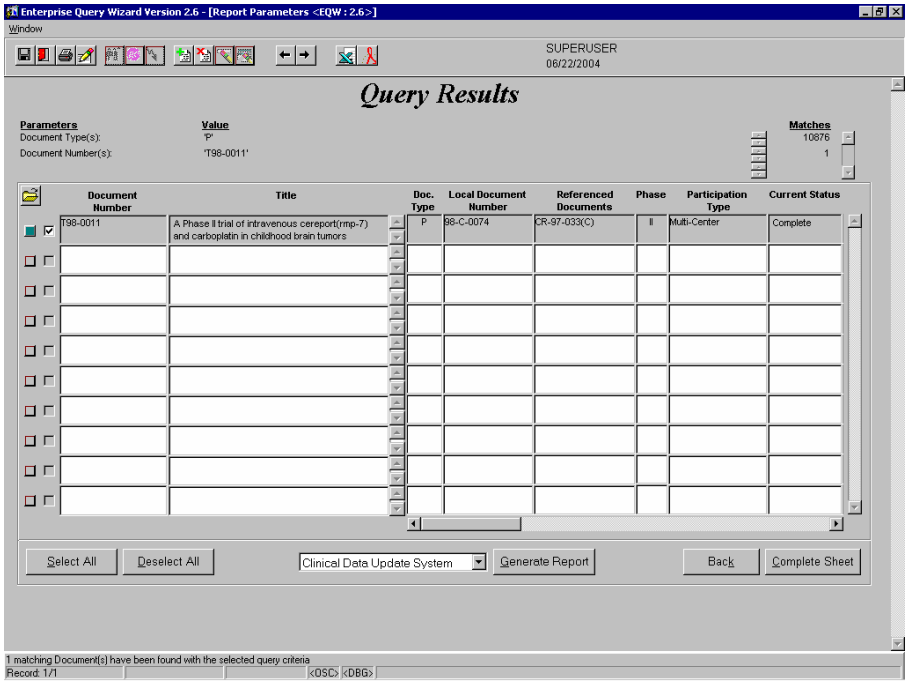


Figure 3 - Query Results

Use the **Back** button to return to the **Query Wizard** screen. Click **Generate Report** to open the CDUS Report Writer.

Using the Home Screen

The CDUS Report Writer's home screen, shown in Figure 4, enables you to run all of the CDUS reports without navigating to another screen.

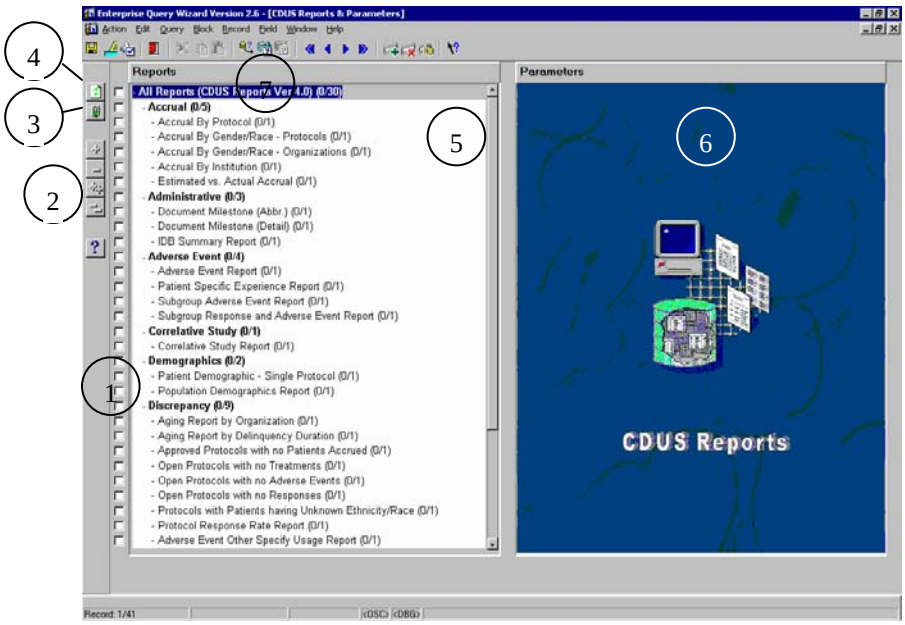


Figure 4 - The CDUS Report Writer Home Screen

The screen's features are explained below:

1 

Select one or more checkboxes to the left of the report names to choose the report to run.

2 

Use the buttons on the left side of the screen to expand or collapse the report menu. Click the single plus sign to expand the list of report categories and the single minus sign to collapse the list of report categories. Click the double-plus sign to list all report categories and reports. Click the double-minus sign to collapse the list of all report categories and reports. The single plus and minus signs expand or collapse each report category to reveal the reports in the category.

3 

Click this button to run a report.

4 

Click this button to refresh the left pane.

5 

The left pane displays the report menu.

6 

When you choose a report, a parameter dialog box opens in the right pane.

7 

The count, which appears in parentheses next to the report category and report, indicates the number of reports that you have selected in the category and the total number of reports available in the category.

This example shows that all of the Accrual reports (3/3) are selected and all of the Accrual By Protocol Reports (1/1) are selected.

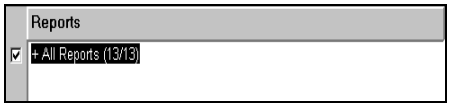
The label *All Reports* at the top of the left pane shows the number of reports that you have selected and the total number of reports available.

Running Reports

As mentioned earlier in this section, you can run all of the CDUS reports without navigating to another screen. Select and run the reports in the same manner, but select different parameters for each report. The *Running the Report* section for each report provides a listing of parameters.

To run a CDUS report:

1. Select *All Reports* at the top of the left pane, as shown below.



2. Highlight one or more checkboxes to the left of the report menu to choose the report to run. A parameters dialog box will open in the right pane, as shown in Figure 5.

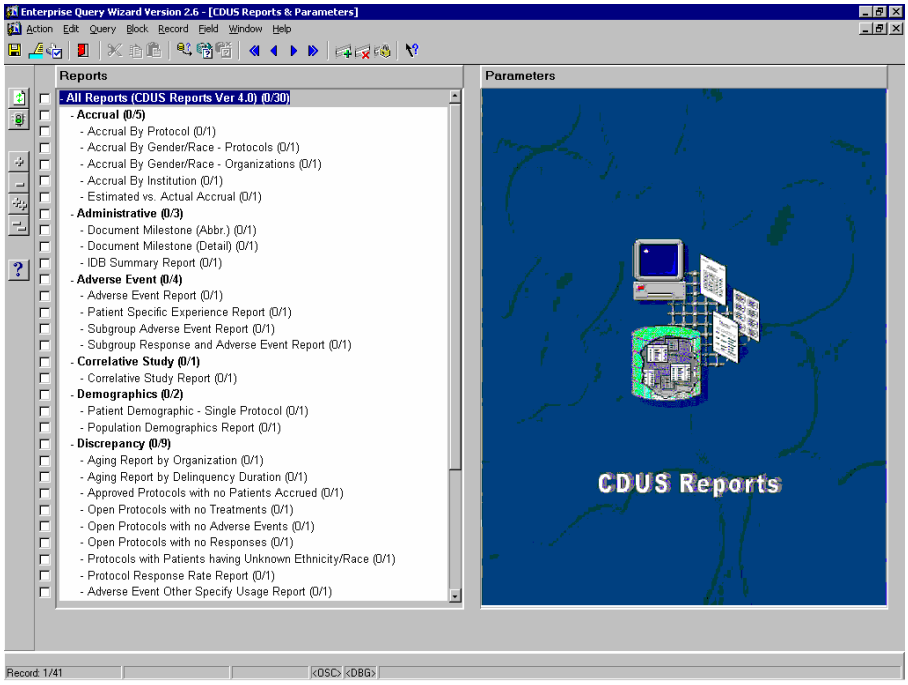


Figure 5 - Report Writer Home Screen with Parameter Dialog Box

In the Parameters dialog box, the Report Parameters set limits to the data that will be included in the report.

3. Select report parameters from the dropdown list boxes.

   The Output Parameters determine how the report will be viewed and saved.

4. Select **Preview** to view the report in a preview screen.

   -or-

   Select **File** from the Output Type dropdown list to save the document without previewing it. Select PDF from the Output Format dropdown list.

The Accrual Reports

The Accrual By Protocol Report

The Accrual By Protocol report counts how many patients are accrued for a particular Protocol Number (document number). Group the results by Phase and Status. Only protocols with a monitoring method of CDUS- Abbreviated or CDUS-Complete or CTMS (CDUS - Abbreviated) or CTMS (CDUS - Complete) are displayed. If no patients have been accrued on the protocol, the protocol will appear on the report with a total = zero.

Running the Report

1. Click the checkbox to the left of **Accrual By Protocol**.

   Parameters appear in the right frame as shown in Figure 6.

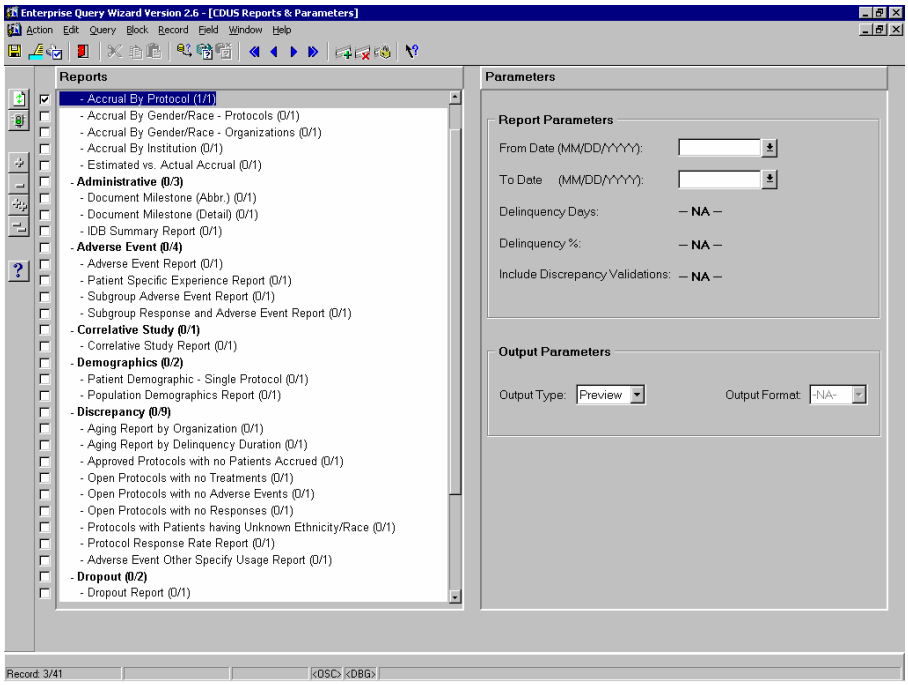


Figure 6 - Accrual by Protocol Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run.**

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

The columns displayed on the report are:

- Organization ID: Lead Organization of the protocol
- Protocol Number: Protocol Number
- Title: Tile of the protocols
- Phase: Phase of the protocol
- Status: Current Status of the Protocol
- Organization Type: Type of organization participating
- Grand Total: Grand total of patients accrued
- Total: Total number of accrual of patients for that protocol

Business Rules

Business rules do not determine this report's output.

Enhancements

With CDUS Report Writer version 3.0 and future releases, if there are no accruals then the report will display the protocol with the total as zero.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Accrual By Protocol

Date: 01/30/2003

Organization : NCIPOB - National Cancer Institute Pediatric Oncology Branch

Protocol Number	Title	Phase	Status	Status Date	Participation Type	Cutoff Date	Total
T98-0011	A Phase II trial of intravenous cereport(rmp-7) and carboplatin in childhood brain tumors	II	Active	01/31/1999	Multi-Center	04/03/2002	17

Total : 17

Grand Total : 17

Figure 7 – Sample Accrual By Protocol Report

The Accrual By Gender/Race – Protocols Report

This matrix report displays the total accrual of patients broken down by race and gender, where gender is represented on the x-axis and race on the y-axis. The total accrual on an inter-group trial includes all participants.

Running the Report

1. Click the checkbox to the left of **Accrual By Gender/Race Protocols**.

Parameters appear in the right frame as shown Figure 8.

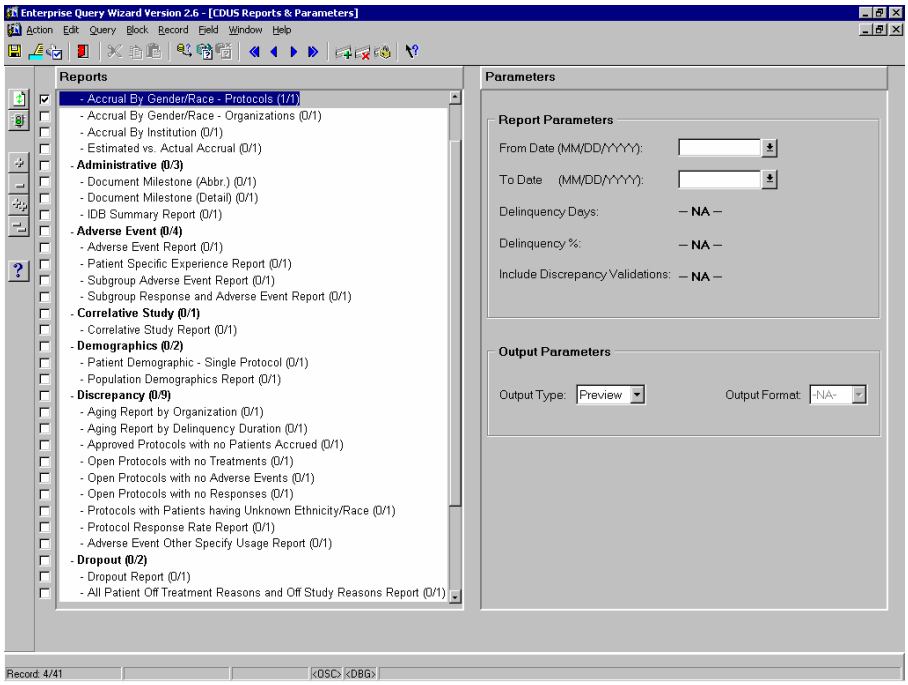


Figure 8 - Accrual by Gender/Race Protocols Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

The columns displayed on the report are:

- Race

- Gender

Business Rules

Business rules do not govern the results of this report.

Enhancements

With CDUS Report Writer version 3.0 and future releases, the report displays all races and gender, including the value of "More than one race." If there are no patients for a race/gender, then the report displays the race/gender with the count of zero.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Accrual by Gender/Race - Protocol(s)

Document Number	Gender / Race	Female	Male	Unknown	Total
T98-0011	Asian	0	0	0	**0**
	Black or African American	1	1	0	**2**
	Native Hawaiian or Other Pacific Islander	0	0	0	**0**
	White	3	7	0	**10**
	American Indian or Alaska Native	1	0	0	**1**
	Unknown	2	2	0	**4**
	More than one race	0	0	0	**0**
	Total	**7**	**10**	**0**	**17**
				Grand Total	**17**

Figure 9 – Sample Accrual By Gender/Race - Protocols Report

The Accrual By Gender/Race - Organizations Report

This matrix report displays the total accrual of patients broken down by race and gender, where gender is represented on the x-axis and race on the y-axis. Total accrual is grouped by organization ID.

Running the Report

1. Click the checkbox to the left of **Accrual By Gender/Race – Organizations**.

Parameters appear in the right frame as shown in Figure 10.

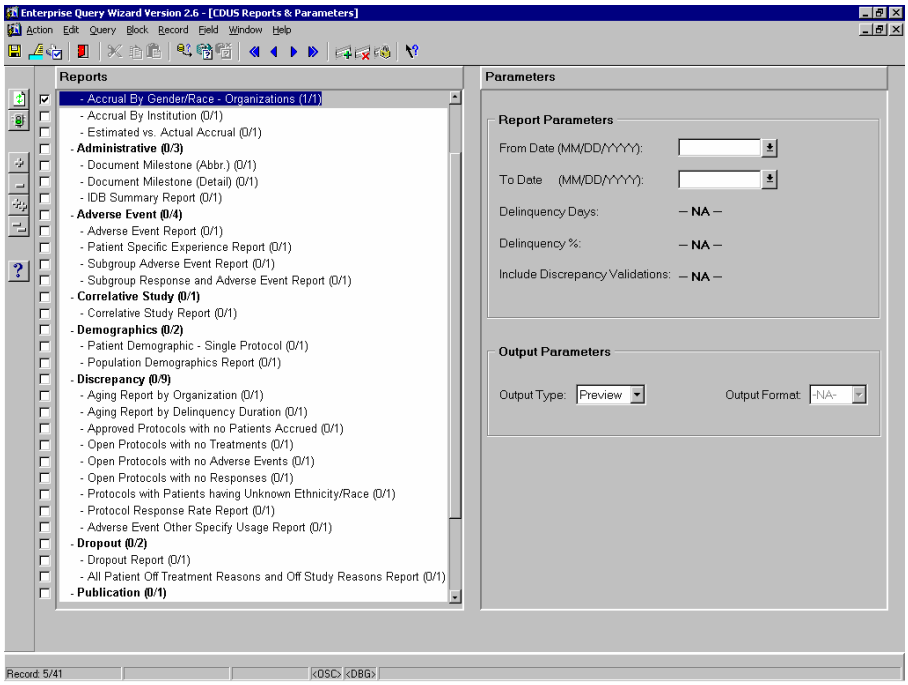


Figure 10 - Accrual by Gender/Race – Organizations Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

The columns displayed on the report are:

- Organization
- Race
- Gender

Business Rules

If Participation Type of protocol = “Intergroup,” accrual data is reported by Registering Institution ID (not Lead Org).

Enhancements

With CDUS Report Writer version 3.0 and future releases, the report displays all races and gender, including the value of “More than one race.” If there are no patients for a race/gender, then the report displays the race/gender with the count of zero.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Accrual By Gender/Race - Organizations

Organization	Gender / Race	Female	Male	Unknown	Total
NCIPOB - National Cancer Institute Pediatric Oncology Branch	Asian	0	0	0	**0**
	Black or African American	1	1	0	**2**
	Native Hawaiian or Other Pacific Islander	0	0	0	**0**
	White	3	7	0	**10**
	American Indian or Alaska Native	1	0	0	**1**
	Unknown	2	2	0	**4**
	More than one race	0	0	0	**0**
	Total	**7**	**10**	**0**	**17**
				Grand Total	**17**

Figure 11 – Sample Accrual By Gender/Race - Organizations Report

The Accrual By Institution Report

This matrix report displays the total accrual of patients for a protocol by institution. Total accrual is grouped by organization ID.

Running the Report

1. Click the checkbox to the left of **Accrual by Institution**.

Parameters appear in the right frame as shown in Figure 12.

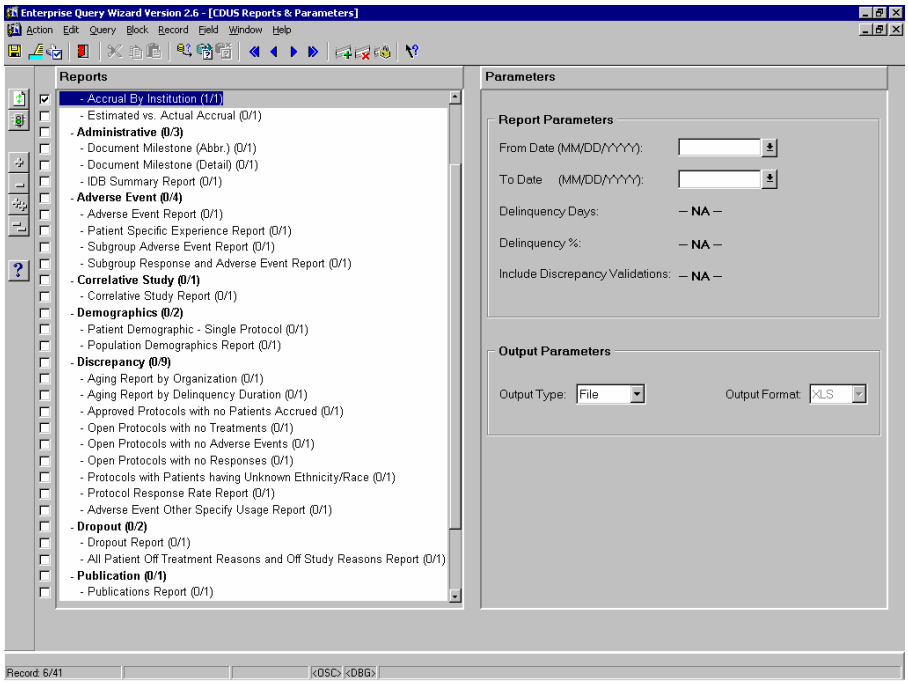


Figure 12 - Accrual by Institution Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

This report does not have fields that need to be defined.

Business Rules

Institutions with accrual that are not participating institutions on the protocol are marked with asterisks.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Accrual By Institution

	T98-0011 AC 01/31/1999	Total
Beth Israel Medical Center (NY003)	*1	1
Children's Cancer Group (CCG)	0	0
Children's Hospital and Regional Medical Center (WA061)	*3	3
Children's Oncology Group (COG)	0	0
Childrens Hospital of Pittsburgh (PA010)	*1	1
Childrens National Medical Center (DC008)	*5	5
M.D. Anderson Cancer Center (FL020)	*2	2
M.D. Anderson Cancer Center (TX035)		0
National Cancer Institute Pediatric Oncology Branch (NCIPOB)	3	3
University of California San Francisco Medical Center (CA385)	*2	2
Total	17	17

* denotes that the institution was not listed in the system as a participating institution for the protocol.

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Figure 13 – Sample Accrual By Institution Report

The Estimated vs. Actual Accrual Report

This report displays the subgroup, treatment, response, and toxicity. The report is similar to the Response and Adverse Event Report, except that the treatments are broken down by subgroup.

Running the Report

1. Click the checkbox to the left of **Estimated vs. Actual Accrual**.

Parameters appear in the right frame as shown in Figure 19.

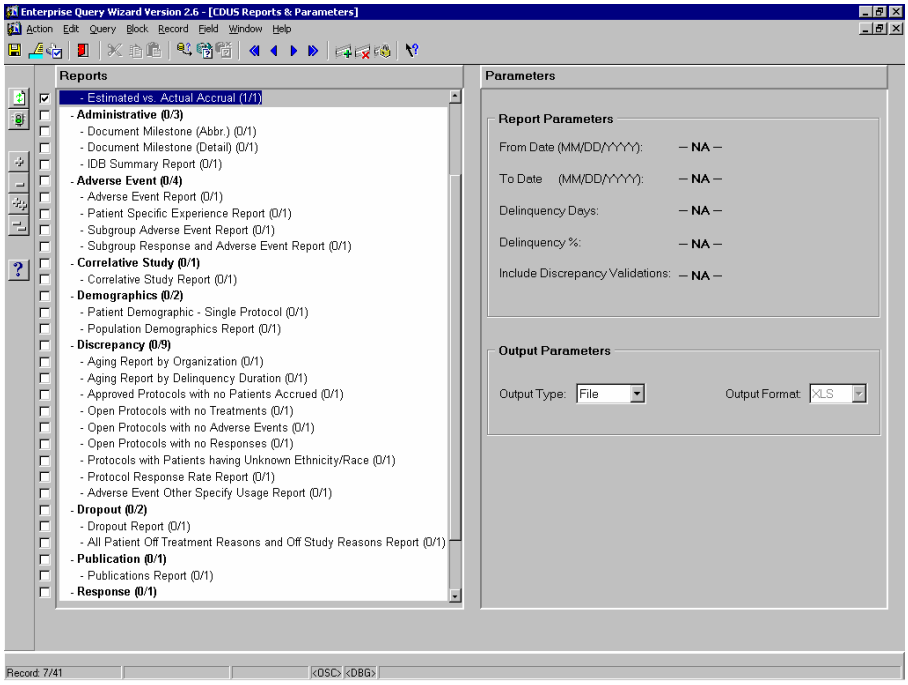

Figure 14 – Estimated vs. Accrual Parameters

2. Click **Run**.

   The Estimated vs. Actual Accrual dialog box displays, as shown in Figure 15, Figure 16, and Figure 17.

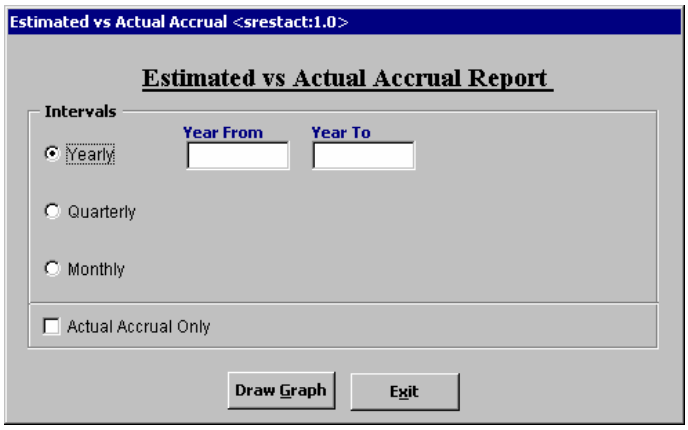

Figure 15 – Estimated vs. Accrual Yearly Parameters

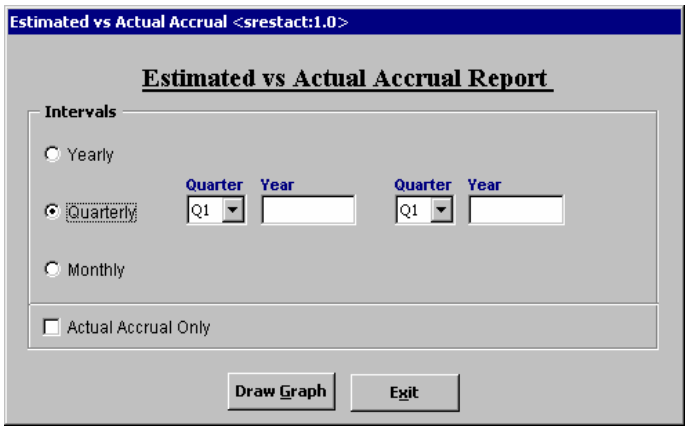

Figure 16 – Estimated vs. Accrual Quarterly Parameters

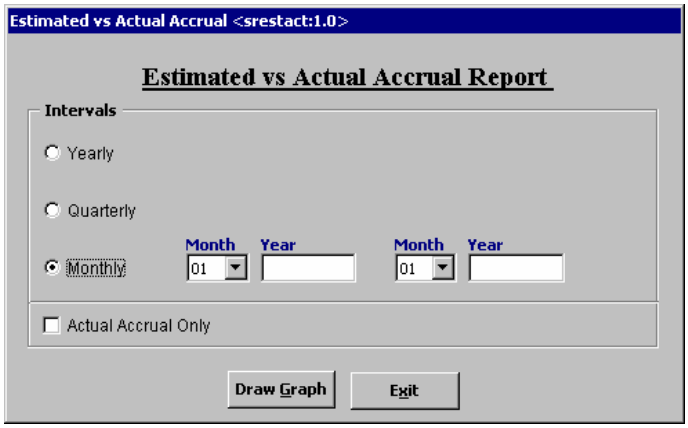

Figure 17 – Estimated vs. Accrual Monthly Parameters

3. Select an Interval (**Yearly**, **Quarterly**, or **Monthly**) and date range.
4. Select the Actual Accrual Only option if you do not wish to view the estimated accrual.
5. When finished, click **Draw Graph** to generate the report, or **Exit** to close the dialog box and return to the CDUS Report Writer home screen.

Changing the Report Output

The report output can be limited by the following parameters:

- Interval (Yearly, Quarterly, or Monthly)
- Protocol Number
- Date of Entry Range (from and to dates)
- Organization ID
- Accrual

Field Definitions

This report does not have fields that need to be defined.

Business Rules

Actual Accrual data reported is always cumulative through the "To Date." The Actual Accrual is not just a count of the patients accrued during the date range specified.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

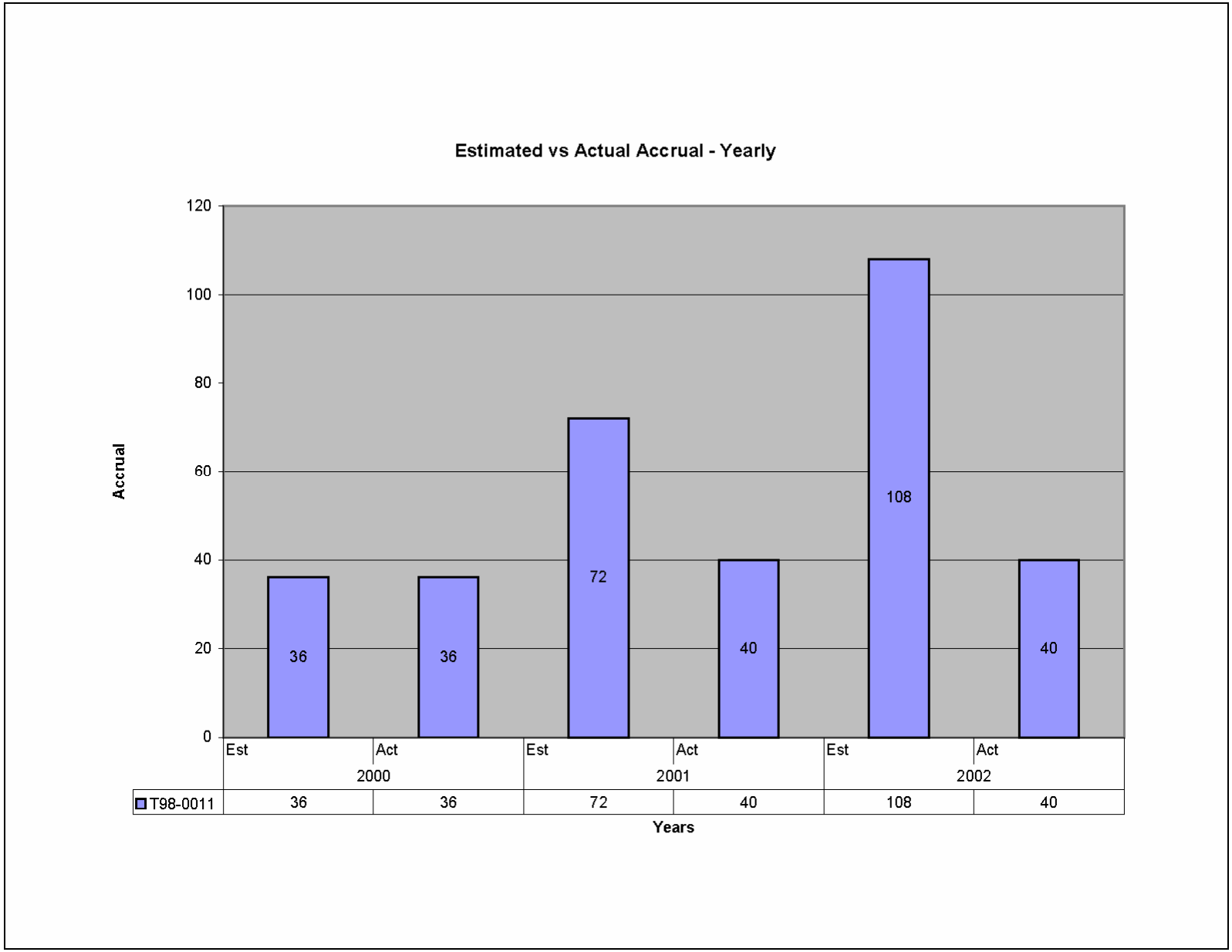

Figure 18 – Sample Accrual By Institution Report

The Administrative Reports

The Document Milestone (Abbr.) Report

This report displays the abbreviated version of the document milestones.

Running the Report

1. Click the checkbox to the left of **Document Milestone (Abbr.) Report**.

Parameters appear in the right frame as shown in Figure 19.

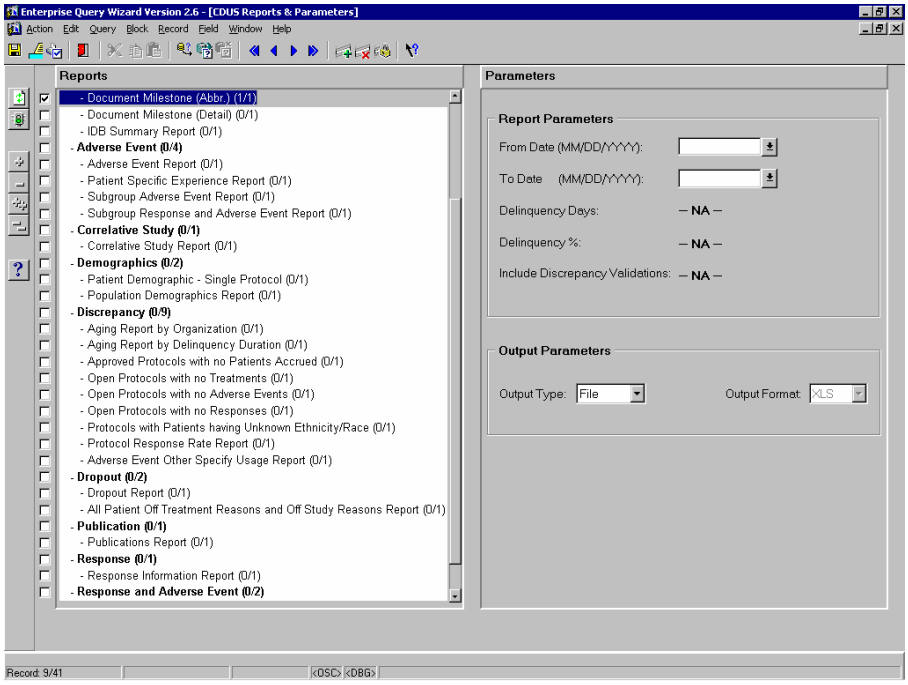

Figure 19 - Document Milestone (Abbr.) Report Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.

4. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates) based on patient's Date of Entry

Field Definitions

- **Document Number:** The identification number of the clinical trial document from which the information shown is referenced.
- **Lead Organization:** The name and unique CTEP ID of the lead organization participating in the protocol.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Funding Information:** Indicates the NCI Program/Division that is the trial sponsor. Sponsorship includes the provision of funding.
- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Doc Type:** The type of document from which clinical trial information is referenced. A single letter represents each document type: C – Concept Review; L – Letter of Intent (LOI); and P – Protocol.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Current Status:** The current status of the document as entered in PATS.

The remaining fields for this report are populated only for protocols.

- **LOI Approval Date:** The date on which the letter of intent was approved.
- **Date of Protocol Receipt:** The date during which the protocol information office (PIO) received the document (LOI, Concept Review, or Protocol).
- **Review Date:** The date the review was conducted for a specified document.
- **Revisions Received Date(s):** The date the revisions were received for a specified document.

- **Approval Date:** The date on which the protocol was approved.
- **Activation Date:** The activation date for the protocol as entered in PATS
- **Closed to Accrual Date:** Date on which protocol status was changed to closed to accrual.
- **Total Accrual**: Number of patients accrued for the study.
- **Cutoff Date**: The cutoff date for the data displayed for the protocol as submitted using CDUS.

Business Rules

Business rules do not determine this report's output.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Document Milestones

Document Number	Lead Organization	Lead Disease	Funding Information	Title	Doc Type	Phase	Current Status
T98-0011	National Cancer Institute Pediatric Oncology Branch (NCIPOB)	Anaplastic astrocytoma	U10 CA 13539	A Phase II trial of intravenous cereport(rmp-7) and carboplatin in childhood brain tumors	P	II	Active

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Figure 20 – Sample Document Milestone (Abbr.) Report (page 1 of 2)

Document Milestones

Document Number	LOI Approval Date	Date of Protocol Receipt	Review Date	Revisions Received Date(s)	Approval Date	Activation Date	Closed to Accrual Date	Total Accrual	Cutoff Date
T98-0011		02/17/1998	03/05/1998	04/20/1998	05/05/1998	01/31/1999		17	04/03/2002

Figure 21 - Sample Document Milestone (Abbr.) Report (page 2 of 2)

The Document Milestone (Detail) Report

This report displays the detailed version of the document milestones.

Running the Report

1. Click the checkbox to the left of **Document Milestone (Detail) Report**.

Parameters appear in the right frame as shown in Figure 22.

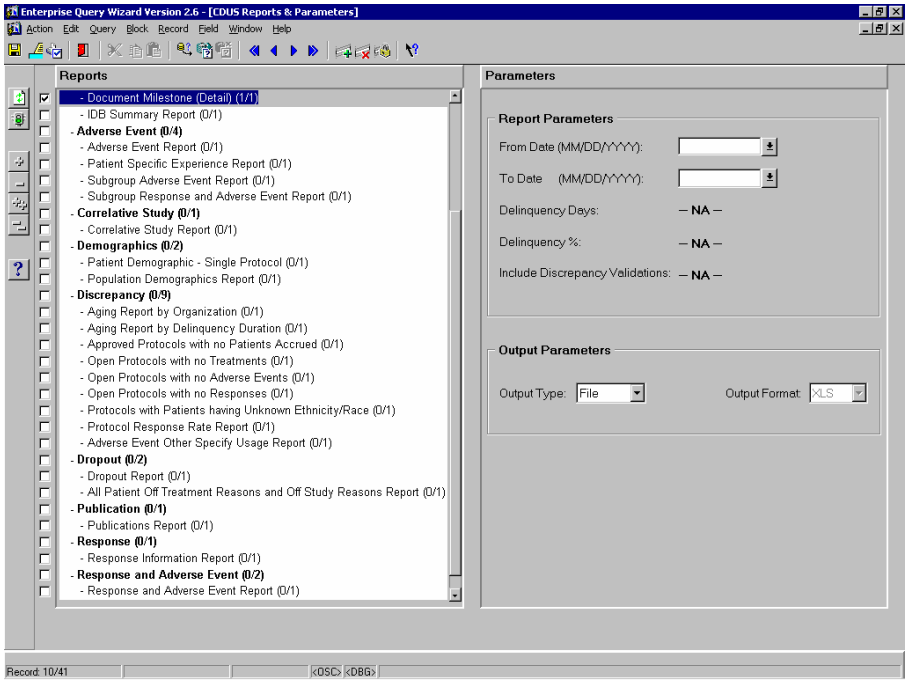


Figure 22 - Document Milestone (Detail.) Report Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

- **Document Number:** The identification number of the clinical trial document from which the information shown is referenced.

- **Lead Organization:** The name and unique CTEP ID of the lead organization participating in the protocol.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Funding Information:** Indicates the NCI Program/Division that is the trial sponsor. Sponsorship includes the provision of funding.
- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Doc Type:** The type of document from which clinical trial information is referenced. A single letter represents each document type: C – Concept Review; L – Letter of Intent (LOI); and P – Protocol.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Other Agent:** Other agents on the protocol.
- **Therapies:** Other therapies on the protocol.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.

The remaining fields for this report are populated only for protocols.

- **LOI Approval Date:** The date on which the LOI was approved.
- **Date of Protocol Receipt**: The date during which the protocol information office (PIO) received the document (LOI, Concept Review, or Protocol).
- **Review Date**: The date the review was conducted for a specified document.
- **Revisions Received Date(s):** The date the revisions were received for a specified document.

- **Approval Date** — The date on which the protocol was approved.
- **Activation Date** — The activation date for the protocol as entered in PATS.
- **Closed to Accrual Date** — Date on which protocol status was changed to closed to accrual.
- **Planned Accrual Rate (Monthly)** — The planned monthly range of patient accrual.
- **Planned Accrual (Max)** — The planned range of patient accrual. The minimum accrual + "-" + the maximum accrual is displayed as entered in PATS.
- **Actual Accrual Rate** — The rate at which patients were actually accrued for a protocol.
- **Total Accrual** — Number of patients accrued for the study.
- **Cutoff Date** — The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Submission Date** — The last date that data was submitted through CDUS for the protocol.

Business Rules

Business rules do not determine this report's output.

Enhancements

With CDUS Report Writer version 4.0 and future releases, the accrual rate is calculated based on when a study is Temporarily Closed to Accrual, Temporarily Closed to Accrual & Treatment, Closed to Accrual, or Closed to Accrual & Treatment. The accrual rate calculation stops when the study is Closed to Accrual and also excludes any time when the study was temporarily closed. If there is no Closed to Accrual status for the specific protocol, then the status of Closed to Accrual & Treatment, Complete or Administratively Complete would be used.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Document Milestones

Document Number	Lead Organization	Principal Investigator	Funding Information	Title	Doc Type	Phase	Lead Disease
T98-0011	National Cancer Institute Pediatric Oncology Branch (NCIPOB)	Warren,Katherine E.	U10 CA 13539	A Phase II trial of intravenous cereport(rmp-7) and carboplatin in childhood brain tumors	P	II	Anaplastic astrocytoma

Page 1 of 4

Figure 23 – Sample Document Milestone (Detail) Report (page 1 of 4)

Document Milestones

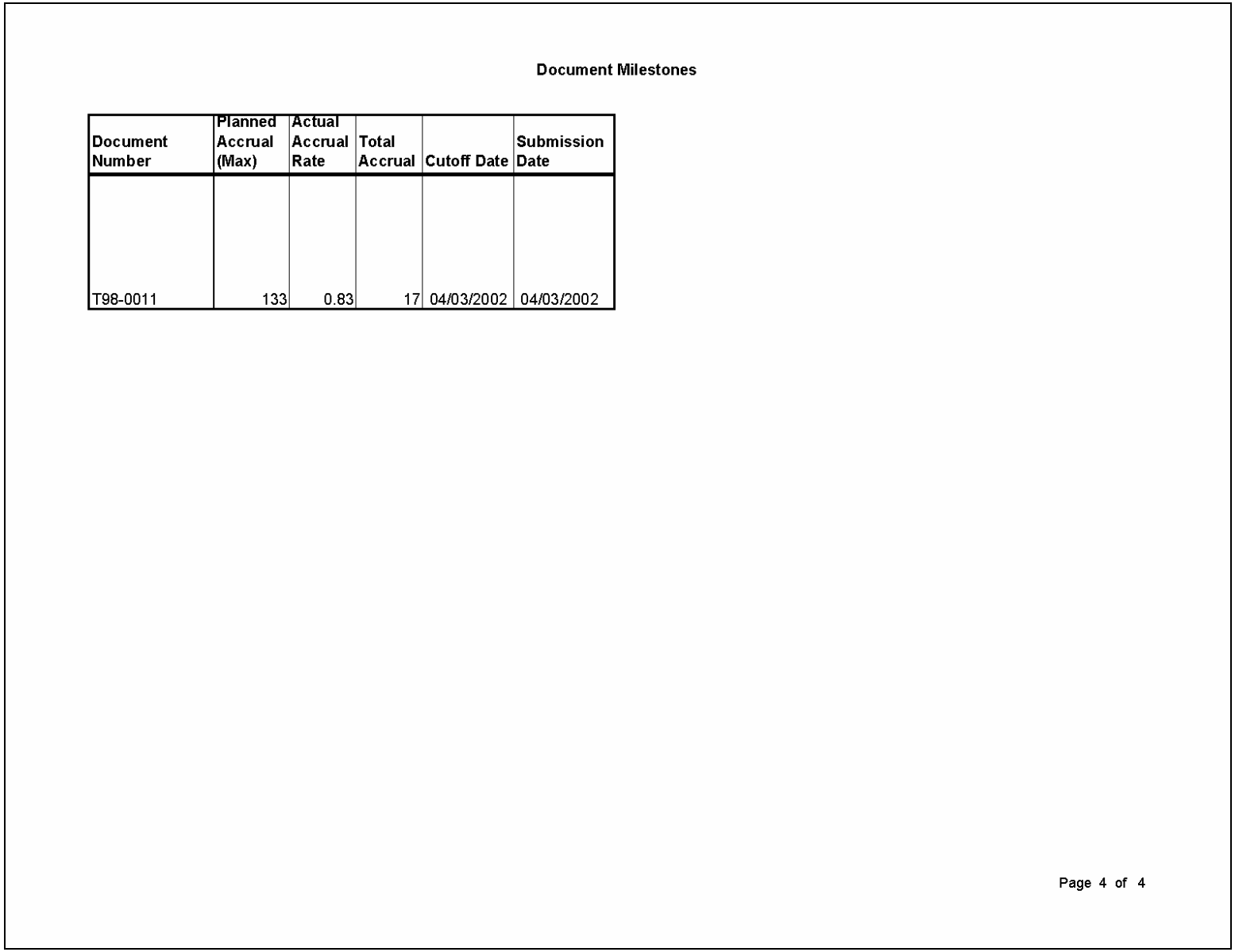
Document Number	Lead IND	Lead Agent	Other Agent	Therapies	Current Status
T98-0011	50733	241240 CARBOPLATIN	266046 OXALIPLATIN,104801 SODIUM BROMEBRATE/CYTEMBENA,127716 5-AZA-2'-DEOXYCYTIDINE(DECITABINE),1 STERILE 0.01N HCL,367982 INTERFERON ALPHA-2A	Chemotherapy (NOS),Therapy (NOS)	Active

Figure 24 – Sample Document Milestone (Detail) Report (page 2 of 4)

Document Milestones

Document Number	Current Status Date	LOI Approval Date	Date of Protocol Receipt	Review Date	Revisions Received Date(s)	Approval Date	Activation Date	Closed to Accrual Date	Planned Accrual Rate(Monthly)
T98-0011	01/31/1999		02/17/1998	03/05/1998	04/20/1998	05/05/1998	01/31/1999		3

Figure 25 – Sample Document Milestone (Detail) Report (page 3 of 4)



Document Milestones

Document Number	Planned Accrual (Max)	Actual Accrual Rate	Total Accrual	Cutoff Date	Submission Date
T98-0011	133	0.83	17	04/03/2002	04/03/2002

Page 4 of 4

Figure 26 – Sample Document Milestone (Detail) Report (page 4 of 4)

The IDB Summary Report

This report displays the IDB Summary Report in a spreadsheet format, which comprises four worksheets: 1) IDB Summary Report, 2) IDB Summary Report (Sort), 3) Report Parameters, and 4) Column Definitions. The report's column headers have auto filter capabilities, and the Page Setup defaults to legal-size paper.

Running the Report

1. Click the checkbox to the left of **IDB Summary Report**.

Parameters appear in the right frame as shown in Figure 27.

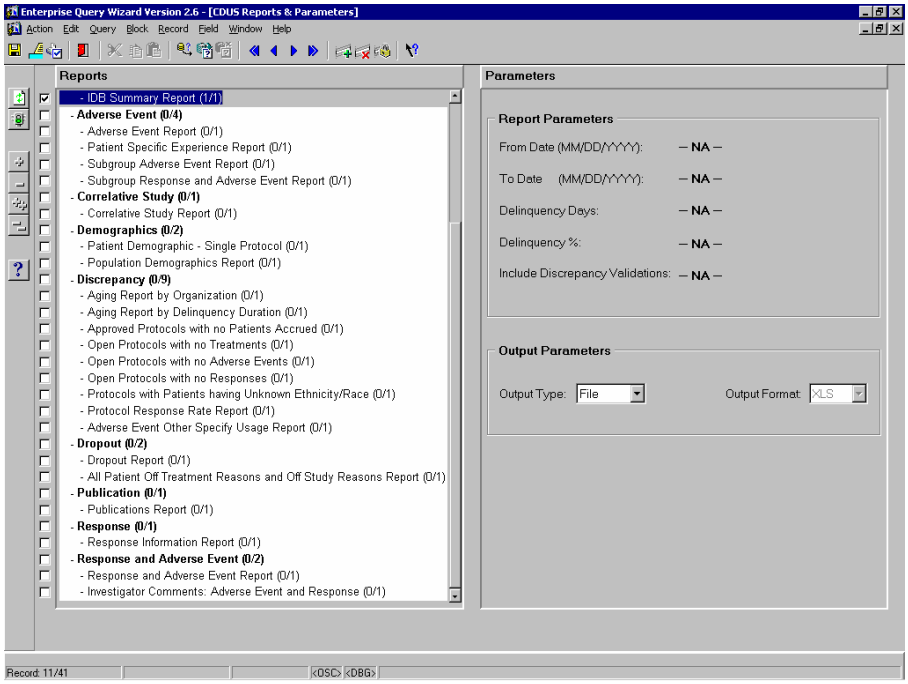


Figure 27 - IDB Summary Report Parameters

2. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Document Type** — Denotes whether the document is of type LOI (L), Concept (C), or Protocol (P).
- **Document Number** — Denotes the NCI CTEP Document Number of the study.

• **Title**	Represents the title of the document.
• **Phase**	Represents the phase of the study, e.g. I, II, III, etc.
• **Current Status**	Represents the status currently assigned to the study.
• **Current Status Date**	Represents the date that the current status became effective.
• **Lead Organization**	Represents the organization that takes responsibility for the trial.
• **Principal Investigator**	Represents the investigator responsible for the trial.
• **Lead Agent**	Represents the agent (in most cases 'Investigational') that is the focus of the study.
• **Lead Disease (CTEP Simplified)**	Represents the primary CTEP Simplified Disease term on the study.
• **Lead IND Number**	Represents the IND used for the lead agent.
• **Activation Date**	Represents the date the trial was first activated.
• **Accrual**	Represents the number of patients currently enrolled in the study.
• **Target Accrual**	Represents the target accrual planned for the study (Minimum target accrual – Maximum Target Accrual)
• **Cut-off Date**	Represents the most recent date for which any data were used in compiling results and reflects the latest date for which information is known.
• **Subgroup (Code) - Description**	A unique code and description used to identify each patient grouping included in a study.
• **Treatment Arm(TAC) - Description**	A unique code and description to identify each dose level or arm included in a study.
• **Subgroup Code - TAC**	Represents the different combinations possible of subgroups and TACs (arms). (codes used) TOTAL is also represented in this column as well as the subgroups not in combination with TAC.
• **Evaluable Patients**	Represents the number of patients evaluable for response.
• **CR**	Represents the number of patients that had a 'Complete Response' for any of the above combinations. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)

- **PR** — Represents the number of patients with the response of 'Partial Response' if the patient has not reported a 'Complete Response'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)

- **SD** — Represents the number of patients with the response of 'Less than Partial Response' or 'Stable' if the patient has not reported a 'Complete Response' or 'Partial Response'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)

- **PD** — Represents the number of patients with the response of 'Progression' if the patient has not reported a 'Complete Response', 'Partial Response', 'Less than Partial Response' or 'Stable'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)

- **OTHER** — Represents the number of patients with the response of 'Other' or 'Not assessed adequately' if the patient has not reported a 'Complete Response', 'Partial Response', 'Less than Partial Response', 'Stable' or 'Progression'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)

- **Grade 3 AEs (N of Patients) w/positive attribution** — Represents the Grade 3 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was 'Possible', 'Probable', or 'Definite')

- **Grade 4 AEs (N of Patients) w/positive attribution** — Represents the Grade 4 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was 'Possible', 'Probable', or 'Definite')

- **Grade 5 AEs (N of Patients) w/positive attribution** — Represents the Grade 5 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was 'Possible', 'Probable', or 'Definite')

- **Grade 3 AEs (N of Patients) regardless of attribution** — Represents the Grade 3 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)

• **Grade 4 AEs (N of Patients) regardless of attribution**	Represents the Grade 4 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)
• **Grade 5 AEs (N of Patients) regardless of attribution**	Represents the Grade 5 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)
• **Document Type**	Denotes whether the document is of type LOI (L), Concept (C), or Protocol (P).
• **Document Number**	Denotes the NCI CTEP Document Number of the study.
• **Title**	Represent the title of the document.
• **Phase**	Represents the phase of the study, e.g. I, II, III, etc...
• **Current Status**	Represents the status currently assigned to the study.
• **Current Status Date**	Represents the date that the current status became effective.
• **Lead Organization**	Represents the organization that takes responsibility for the trial.
• **Principal Investigator**	Represents the investigator responsible for the trial.
• **Lead Agent**	Represents the agent (in most cases 'Investigational') that is the focus of the study.
• **Lead Disease (CTEP Simplified)**	Represents the primary CTEP Simplified Disease term on the study.
• **Lead IND Number**	Represents the IND used for the lead agent.
• **Activation Date**	Represents the date the trial was first activated.
• **Accrual**	Represents the number of patients currently enrolled in the study.
• **Target Accrual**	Represents the target accrual planned for the study (Minimum target accrual – Maximum Target Accrual)
• **Cut-off Date**	Represents the most recent date for which any data were used in compiling results and reflects the latest date for which information is known.
• **Subgroup (Code) - Description**	A unique code and description used to identify each patient grouping included in a study.

• **Treatment Arm(TAC) - Description**	A unique code and description to identify each dose level or arm included in a study.
• **Subgroup Code - TAC**	Represents the different combinations possible of subgroups and TACs (arms). (codes used)
•	TOTAL is also represented in this column as well as the subgroups not in combination with TAC.
• **Evaluable Patients**	Represents the number of patients evaluable for response.
• **CR**	Represents the number of patients that had a 'Complete Response' for any of the above combinations. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)
• **PR**	Represents the number of patients with the response of 'Partial Response' if the patient has not reported a 'Complete Response'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)
• **SD**	Represents the number of patients with the response of 'Less than Partial Response' or 'Stable' if the patient has not reported a 'Complete Response' or 'Partial Response'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)
• **PD**	Represents the number of patients with the response of 'Progression' if the patient has not reported a 'Complete Response', 'Partial Response', 'Less than Partial Response' or 'Stable'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)
• **OTHER**	Represents the number of patients with the response of 'Other' or 'Not assessed adequately' if the patient has not reported a 'Complete Response', 'Partial Response', 'Less than Partial Response', 'Stable' or 'Progression'. (Please refer to the section *Response Rules when Attributed to Subgroup/TAC Combination* on page 41.)
• **Grade 3 AEs (N of Patients) w/positive attribution**	Represents the Grade 3 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was 'Possible', 'Probable', or 'Definite')
• **Grade 4 AEs (N of Patients)**	Represents the Grade 4 adverse events experienced for patients on the above combinations and displays

w/positive attribution	the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was ‘Possible’, ‘Probable’, or ‘Definite’)
• **Grade 5 AEs (N of Patients) w/positive attribution**	Represents the Grade 5 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (only counted if the attribution was ‘Possible’, ‘Probable’, or ‘Definite’)
• **Grade 3 AEs (N of Patients) regardless of attribution**	Represents the Grade 3 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)
• **Grade 4 AEs (N of Patients) regardless of attribution**	Represents the Grade 4 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)
• **Grade 5 AEs (N of Patients) regardless of attribution**	Represents the Grade 5 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (if available, the short name for the adverse event will be used) (any attribution)

Response Rules when Attributed to Subgroup/TAC Combination

Additional response rules when attributed to Subgroup/TAC combination: It checks to see that the response is counted only once.

(

Patient is counted only when the observed date (minus 3 days) of the response is greater than or equal to the treatment course start date

OR,

no other treatment was taken by the patient before (1st Treatment)

)

AND (

no other treatment course exists with the start date greater than the above treatment courses start date

OR,

the observed date (minus 3 days) of the response is before the following treatment courses start date

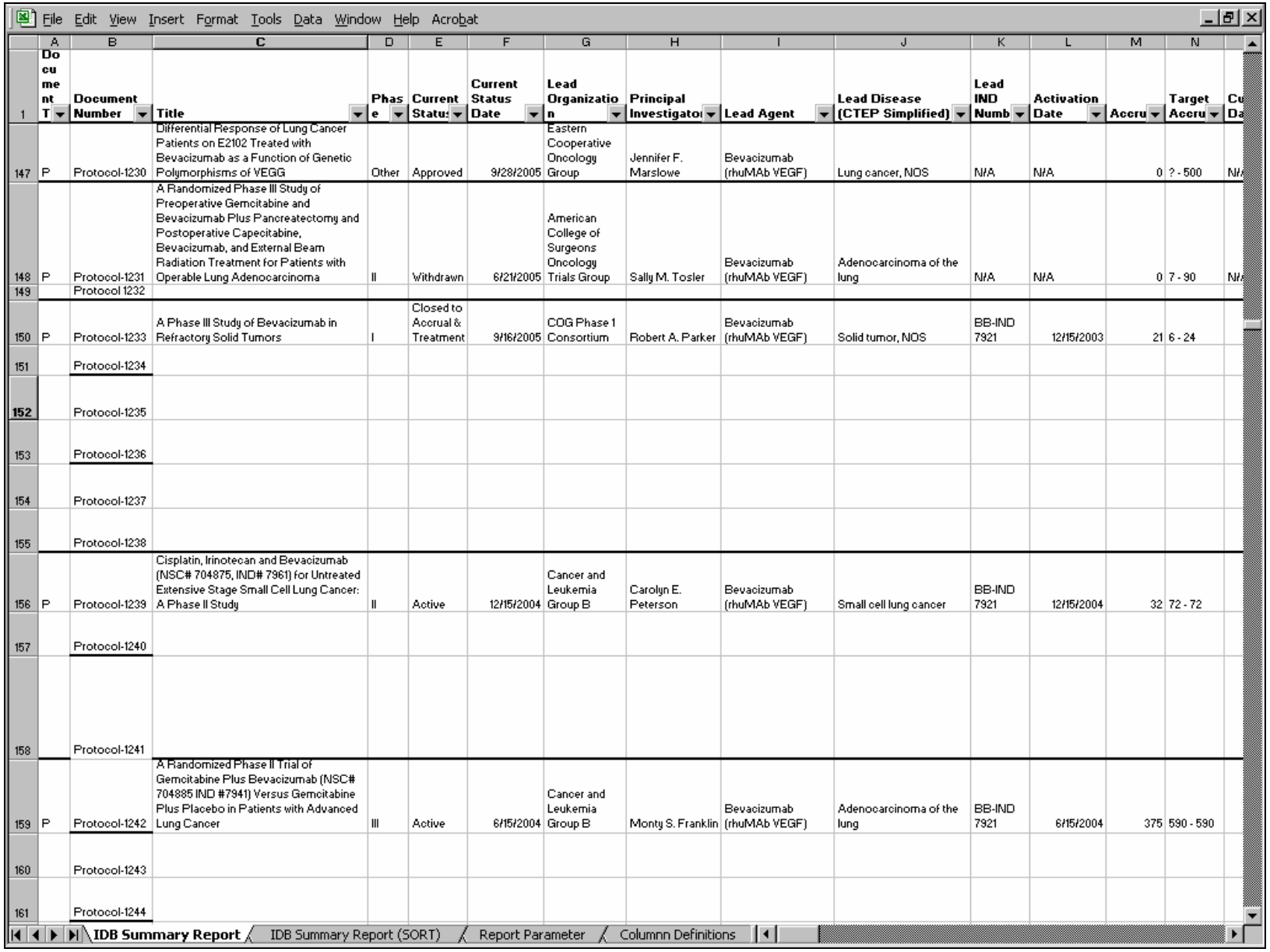
)..

Enhancements

With CDUS Report Writer version 4.0 and future releases, the accrual rate is calculated based on when a study is Temporarily Closed to Accrual, Temporarily Closed to Accrual & Treatment, Closed to Accrual, or Closed to Accrual & Treatment. The accrual rate calculation stops when the study is Closed to Accrual and also excludes any time when the study was temporarily closed. If there is no Closed to Accrual status for the specific protocol, then the status of Closed to Accrual & Treatment, Complete or Administratively Complete would be used.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.



File Edit View Insert Format Tools Data Window Help Acrobat

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	
1	Document T	Document Number	Title	Phase	Current Status	Current Status Date	Lead Organization	Principal Investigator	Lead Agent	Lead Disease (CTEP Simplified)	Lead IND Numb	Activation Date	Accru	Target Accru	Cu Da
147	P	Protocol-1230	Differential Response of Lung Cancer Patients on E2102 Treated with Bevacizumab as a Function of Genetic Polymorphisms of VEGG	Other	Approved	9/28/2005	Eastern Cooperative Oncology Group	Jennifer F. Marslowe	Bevacizumab (rhuMAb VEGF)	Lung cancer, NOS	N/A	N/A	0	? - 500	N/
148	P	Protocol-1231	A Randomized Phase III Study of Preoperative Gemcitabine and Bevacizumab Plus Pancreatectomy and Postoperative Capecitabine, Bevacizumab, and External Beam Radiation Treatment for Patients with Operable Lung Adenocarcinoma	II	Withdrawn	6/21/2005	American College of Surgeons Oncology Trials Group	Sally M. Tosler	Bevacizumab (rhuMAb VEGF)	Adenocarcinoma of the lung	N/A	N/A	0	7 - 90	N/
149		Protocol 1232													
150	P	Protocol-1233	A Phase III Study of Bevacizumab in Refractory Solid Tumors	I	Closed to Accrual & Treatment	9/16/2005	COG Phase 1 Consortium	Robert A. Parker	Bevacizumab (rhuMAb VEGF)	Solid tumor, NOS	BB-IND 7921	12/15/2003	21	6 - 24	
151		Protocol-1234													
152		Protocol-1235													
153		Protocol-1236													
154		Protocol-1237													
155		Protocol-1238													
156	P	Protocol-1239	Cisplatin, Irinotecan and Bevacizumab (NSC# 704875, IND# 7961) for Untreated Extensive Stage Small Cell Lung Cancer: A Phase II Study	II	Active	12/15/2004	Cancer and Leukemia Group B	Carolyn E. Peterson	Bevacizumab (rhuMAb VEGF)	Small cell lung cancer	BB-IND 7921	12/15/2004	32	72 - 72	
157		Protocol-1240													
158		Protocol-1241													
159	P	Protocol-1242	A Randomized Phase II Trial of Gemcitabine Plus Bevacizumab (NSC# 704885 IND #7941) Versus Gemcitabine Plus Placebo in Patients with Advanced Lung Cancer	III	Active	6/15/2004	Cancer and Leukemia Group B	Monty S. Franklin	Bevacizumab (rhuMAb VEGF)	Adenocarcinoma of the lung	BB-IND 7921	6/15/2004	375	590 - 590	
160		Protocol-1243													
161		Protocol-1244													

IDB Summary Report | IDB Summary Report (SORT) | Report Parameter | Column Definitions

Figure 28 – Sample IDB Summary Report

The PI Verification Summary Report

The PI Verification Summary report provides study Principal Investigators with an overview of the data submitted successfully on their behalf to CTEP via the CDUS.

Running the Report

1. Click the checkbox to the left of **PI Verification Summary Report**.

Parameters appear in the right frame as shown Figure 29.

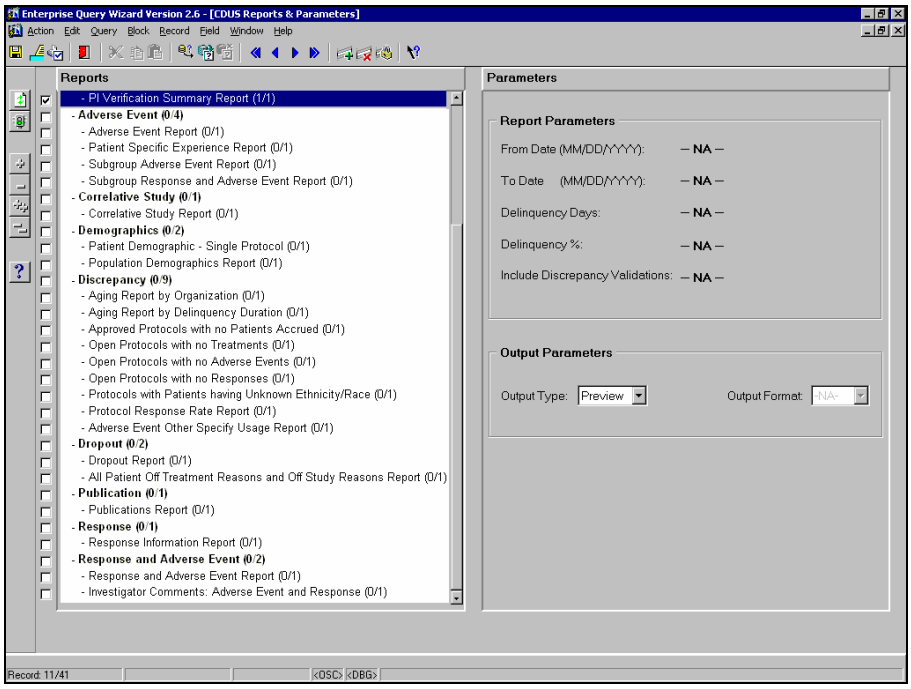


Figure 29 - PI Verification Summary Report Parameters

2. Select **Preview**, **Print**, or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **NCI Document Number** — Denotes the NCI CTEP Document Number of the study.
- **Local Document Number** — Denotes the local Document Number of the study.
- **Phase** — Represents the phase of the study, e.g. I, II, III, etc.
- **Lead Organization** — Represents the organization that takes responsibility for the trial.

- **Trial Status** — Represents the status currently assigned to the study.
- **Trial Status Date** — Represents the date that the current status became effective.
- **Title** — Represents the title of the document.
- **Monitoring Method** — The monitoring method for the protocol as entered in PATS.
- **Person responsible for the data submission (PCDU)** — Name, email, and phone of the PCDU contact.
- **Principal Investigator** — Name, email, and phone of the investigator responsible for the trial.

Accrual

- **Site validated date as of** — The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Entered** — The number of patients entered on the study.
- **On Treatment*** — The number of patients that are currently receiving treatment on the study.
- **Off Study*** — The number of patients who have left the study.
- **Ineligible*** — The number of patients declared ineligible to participate on the study.
- **Evaluable for Response*** — Total number of patients on the study who are evaluable for response as submitted using CDUS.
- **Grade 5 (Death)*** — Represents the number of patients that have experienced a Grade 5 adverse event.
- **Grade 4*** — Represents the number of patients that have experienced a Grade 4 adverse event (only counted if the attribution was 'Possible', 'Probable', or 'Definite' towards the lead agent).

Note: Report items marked with an asterisk (*) appear only if the study is a CDUS - Complete monitored study. CDUS - Abbreviated monitored studies do not collect response and toxicity information.

Patient Specifics

- **Ethnic Category** — The number of patients by ethnicity.

- **Racial Category** The number of patients by race.
- **Sex/Gender** The number of patients by sex/gender.

Note: The counts are broken down by the target accrual as stated in the study and by the actual accrual reported via the CDUS.

Response Specifics*

- **Number Evaluable** Total number of patients on the study who are evaluable for response as submitted using CDUS.
- **Number deemed not Evaluable** Total number of patients on the study who are deemed not evaluable for response as submitted using CDUS.
- **Best Responses** The patient's BEST_RESPONSE as submitted using CDUS. The best response is the response which has the highest order in the response sequence: Complete Response>Partial Responses>Less than Partial Response>Progression>Other.

Note: This section appears only if the study is a CDUS - Complete monitored study.

Adverse Event Specifics*

- **Adverse Event** The name of the adverse event experienced by the patients.
- **Grade 5 (Death)** Represents the Grade 5 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event.
- **Grade 4 (Number of patients experiencing each event)** Represents the Grade 4 adverse events experienced for patients on the above combinations and displays the number of patients that experienced the adverse event. (only counted if the attribution was 'Possible', 'Probable', or 'Definite')

Note: This section appears only if the study is a CDUS - Complete monitored study.

Business Rules

Business rules do not govern the results of this report.

Sample Report

A representation of this report is provided on the following pages. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Run by: HDAVIS
Date: 06/21/2007 09:04 AM

CTEP (CDUS) Data Summary

NCI Document Number	Local Document Number	Phase	Lead Organization	Trial Status	Trial Status Date
T01-0001	CWRU 5297	I	Case Western Reserve University	Closed to Accrual & Treatment	01/23/2003

Title

A Phase I Pharmacokinetic, Pharmacodynamic, and Clinical Study of the Combination of the Angiogenesis Inhibitor SU5416 and Doxorubicin in Inflammatory Breast Cancer

Monitoring Method

CDUS - Complete

Person responsible for the data submission (PCDU) : Linda Kescht **Email :** Linda.Kescht@ust.com **Phone :**

Principal Investigator : Bill Odershall **Email :** **Phone :** 215-844-8572

Accrual

Site-validated data as of	Entered	On Treatment	Off Study	Ineligible	Evaluable for response	Adverse Events (number of patients experiencing)	
						Grade 5 (Deaths)	Grade 4 *
09/30/2005	21	3	3	0	19	0	2

* Only patients who have experienced at least one Grade 4 Adverse Event considered either 'Possible', Probable' or 'Definite' attribution to the Investigational Agent are counted.

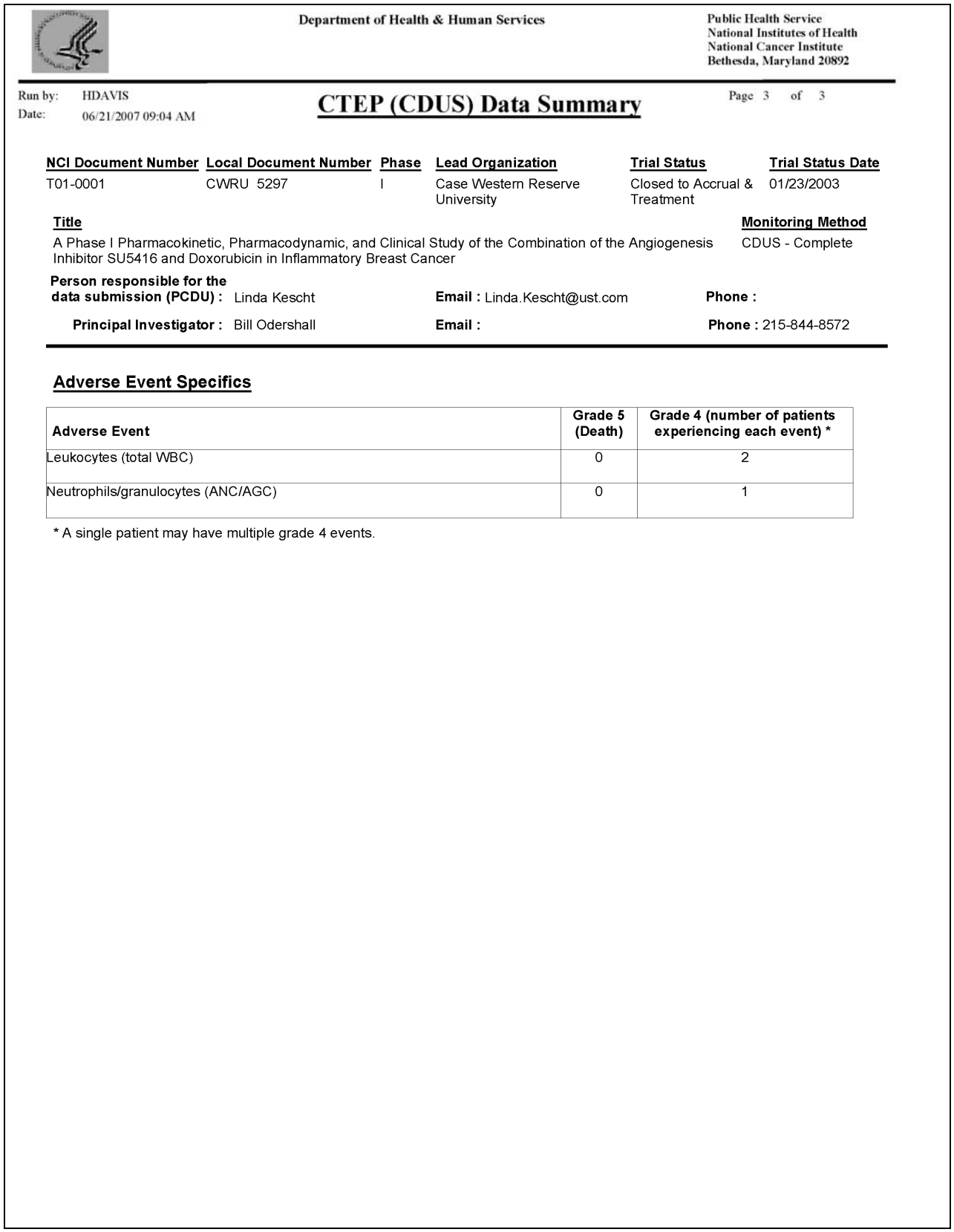
Patient Specifics

Ethnic Category	Sex/Gender						
	Male		Female		Unknown	Total	
	Target	Actual	Target	Actual	Actual	Target	Actual
Hispanic or Latino	0	0	0	0	0	**0**	**0**
Not Hispanic or Latino	0	1	0	20	0	**0**	**21**
Not Reported/Unknown	0	0	0	0	0	**0**	**0**
Total :	**0**	**1**	**0**	**20**	**0**	**0**	**21**
Racial Category							
American Indian or Alaska Native	0	0	0	0	0	**0**	**0**
Asian	0	0	0	0	0	**0**	**0**
Black or African American	0	0	0	1	0	**0**	**1**
Native Hawaiian or Other PacificIslander	0	0	0	0	0	**0**	**0**
Not Reported/Unknown/More than one race	0	0	0	0	0	**0**	**0**
White	0	1	0	19	0	**0**	**20**
Total :	**0**	**1**	**0**	**20**	**0**	**0**	**21**

Response Specifics

Number Evaluable	Number deemed not Evaluable	Best Responses				
		Complete Response	Partial Response	Less than Partial Response	Progression	All Other
19	0	0	0	0	1	18

Figure 30 – Sample PI Verification Summary Report (page 1 of 2)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Run by: HDAVIS
Date: 06/21/2007 09:04 AM

CTEP (CDUS) Data Summary

NCI Document Number	Local Document Number	Phase	Lead Organization	Trial Status	Trial Status Date
T01-0001	CWRU 5297	I	Case Western Reserve University	Closed to Accrual & Treatment	01/23/2003

Title

A Phase I Pharmacokinetic, Pharmacodynamic, and Clinical Study of the Combination of the Angiogenesis Inhibitor SU5416 and Doxorubicin in Inflammatory Breast Cancer

Monitoring Method

CDUS - Complete

Person responsible for the data submission (PCDU) : Linda Kescht **Email :** Linda.Kescht@ust.com **Phone :**

Principal Investigator : Bill Odershall **Email :** **Phone :** 215-844-8572

Adverse Event Specifics

Adverse Event	Grade 5 (Death)	Grade 4 (number of patients experiencing each event) *
Leukocytes (total WBC)	0	2
Neutrophils/granulocytes (ANC/AGC)	0	1

* A single patient may have multiple grade 4 events.

Figure 31 – Sample PI Verification Summary Report (page 2 of 2)

The Adverse Event Reports

The Adverse Event Report

This report summarizes the total number of patients, total number of treatment courses, and the total number of treatment courses for which toxicity has been reported.

Running the Report

1. Click the checkbox to the left of **Adverse Event Report**.

   Parameters appear in the right frame as shown in Figure 32.

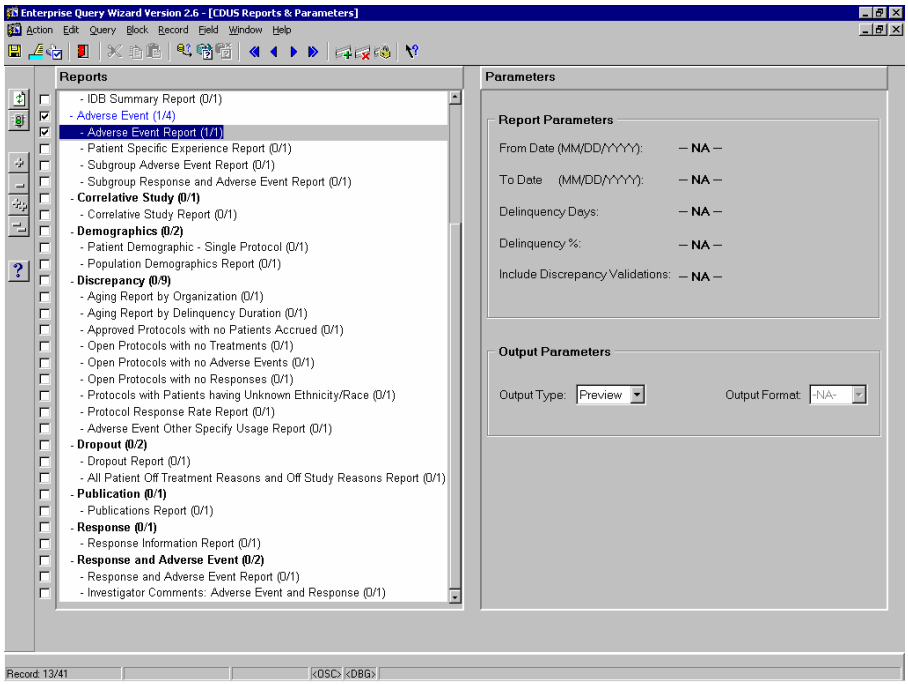


Figure 32 – Adverse Event Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Treatment Assignments:** The treatment assignments are displayed in ascending order by DOSE_LEVEL_ORDER. A secondary sort is on Treatment Assignment code. Only those treatment assignments for which there are data are displayed. If there are no patients entered on a treatment assignment, then that treatment assignment will be left off of the report.

- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type; only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

- **X esc from Y**: The count (**X esc from Y**) is the number of patients who escalated from treatment assignment Y to the current treatment assignment.

- **A Deesc from B:** The count (**A Deesc from B**) is the number of patients who de-escalated from treatment assignment B to the current treatment assignment.

- **The count Z pt. for course 1:** The count **Z pt.** in the course 1 column for a treatment assignment is the number of patients who had toxicities associated with the course (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) that had the minimum COURSE_START_DATE on that treatment assignment.

- **The count Z pt. for course 2+:** The count Z pt. in the course 2+ signifies the number of patients who had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course except the one with the minimum COURSE_START_DATE associated with it. It also signifies those who had the current treatment assignment on their maximum COURSE_START_DATE and the maximum COURSE_START_DATE is not equal to the

minimum COURSE_START_DATE.

- **The count (n= X) for course 1:** The counts **n = X** for course 1 is the sum of the Z pt. counts for all the treatment assignments for course 1.

  Therefore, this is a count of all patients who had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) during their first course of treatment.

- **The count (n= X) for course 2+:** The counts **n = X** for course 2+ is the sum of the Z pt. counts for all the treatment assignments for course 2+.

  Therefore, this is a count of all patients who had toxicity (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course other than their first course of treatment.

- **# started in:** The number of patients who had the course with the minimum COURSE_START_DATE lying in the current treatment assignment.

- **# escalated to:** The number of patients escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

- **Phase:** The phase for the protocol.
- **Lead Organization:** The active lead organization for the protocol + "/ " + the principal investigator for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Activation Date:** The activation date for the protocol as entered in PATS.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered on the protocol.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Planned Accrual:** The planned range of patient accrual. The minimum accrual + "-" + the maximum accrual is displayed as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as

entered in PATS.

- **Prior Therapy Eligibility Criteria:** The prior therapy eligibility criteria for the protocol as entered in PATS.

  If no record is found then the text "N/A" is displayed.

- **Dose Limiting Toxicities:** Dose limiting toxicities for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.

- **Recommended Phase II Dose:** Recommended phase II dose for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.

- **IND:** The lead IND number for the protocol.

- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol.

- **Total # Courses for all Patients:** The total number of courses for all patients on the protocol.

- **Median # Courses/Patient:** The median total number of courses across all patients.

- **Range # Courses/Patient:** The minimum and maximum number of treatment courses received by a patient.

Business Rules

The following business rules determine the report's output:

- **Treatment Assignments:** If there are no patients entered on a treatment assignment, then that treatment assignment will be left off of the report.

- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type, only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

  If the toxicity is associated with the course having the patient's minimum COURSE_START_DATE, then it is displayed under column **Course 1**, otherwise it is displayed under the column **Course 2+**. Toxicities of Grade 1, 2, and 3 with an attribution of "unrelated" or "unlikely" will not be included in the report.

- **X esc from Y**: The count (**X esc from Y** is based on the following logic:

  A patient is escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

- **A Deesc from B:** The count (**A Deesc from B**) is based on the logic that a patient is de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.

- **Prior Therapy Eligibility Criteria:** If no record is found then the text "N/A" is displayed.
- **Dose Limiting Toxicities:** If no record is found then the text "Not Reported" is displayed.
- **Recommended Phase II Dose:** If no record is found then the text "Not Reported" is displayed.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- The protocol status date of the protocol has been added to the header of the report.
- If there are treatments reported on a protocol but not toxicities, the report displays the treatment assignment code and under toxicities says "—No Toxicities Reported—."
- If the Adverse Event type is other, the AE_Other_Specify is displayed.
- Below the treatment assignment, the following is displayed:
  - **# experiencing AE:** The number of patients in the current treatment assignment that have AE experienced = 'Yes.'
  - **# de-escalated to:** The number of patients de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment

assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.

- **# treated:** The number of patients lying in the current treatment assignment.
- **# dose change:** The number of patients lying in the current treatment assignment and had a dose change flag of either 'Yes, planned' or 'Yes, unplanned.'

With CDUS Report Writer version 4.0 and future releases, the report displays the CTCAE version at the top of the report along with the Protocol Number and Title for a study. The Adverse Event information is displayed as a concatenation of the Adverse Event and Select AE.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Clinical Trial Summary: Adverse Event Report

Date : 02/16/2005

CALGB-99903 - A Phase II Study of Arsenic Trioxide (NSC #706363, IND #57974) in Urothelial Cancer

Phase:	II	**CTCAE Version:**	2.0
Lead Organization/PI:	Cancer and Leukemia Group B / Dean F. Bajorin		
Current Status/Date:	Closed to Accrual/ 03/15/2002	**Patients Registered/Treated/On Study:**	13 / 12 / 0
Activation Date:	12/15/2000	**Planned Accrual:**	12 - 35
Cutoff Date:	09/30/2003	**Monitoring Method:**	CDUS - Complete
Dose Limiting Adverse Events:	Not Reported	**Recommended Phase II Dose:**	Not Reported
Lead IND:	57974	**NSC:**	706363 ,ARSENIC TRIOXIDE (Trisenox)
Total # of Courses (for all patients):	28	**Median # of Courses (per patient):**	2
		Range # of Courses (per patient):	1-8

Treatment Assignment

TA1 : ARSENIC TRIOXIDE 0.3mg/KG IV over 1 hour daily for 5 day(s) every 28 days.

# experiencing AE:	11
# started in:	12
# escalated to:	0
# de-escalated to:	0
# treated:	12
# dose change:	3

		AE Reported Course 1 (n=10) **					AE Reported Course 2+ (n=2) **				
	Grade:	**1**	**2**	**3**	**4**	**5**	**Grade:**	**1**	**2**	**3**	**4**	**5**
		10 pts.						2 pts.				
ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	1										
BLOOD/BONE MARROW	Hemoglobin	2	3	1					1			
	Leukocytes (total WBC)	1	1						1			
	Lymphopenia		1									
	Neutrophils/granulocytes (ANC/AGC)		1	1					1			
	Platelets	1	1									
CARDIOVASCULAR (ARRHYTHMIA)	Palpitations	1										
CARDIOVASCULAR (GENERAL)	Edema	4	1					1				
	Hypotension		1									
	Thrombosis/embolism				2						1	

** This report includes grade 3, 4 and 5 events regardless of attribution and grades 1 and 2 events with a possible to definite attribution.

Figure 33 – Sample Adverse Event Report

The Patient Specific Experience Report

The Patient Specific Experience Report provides information about specific toxicities and patients.

Running the Report

1. Click the checkbox to the left of **Patient Specific Experience Report**.

Parameters appear in the right frame as shown in Figure 34.

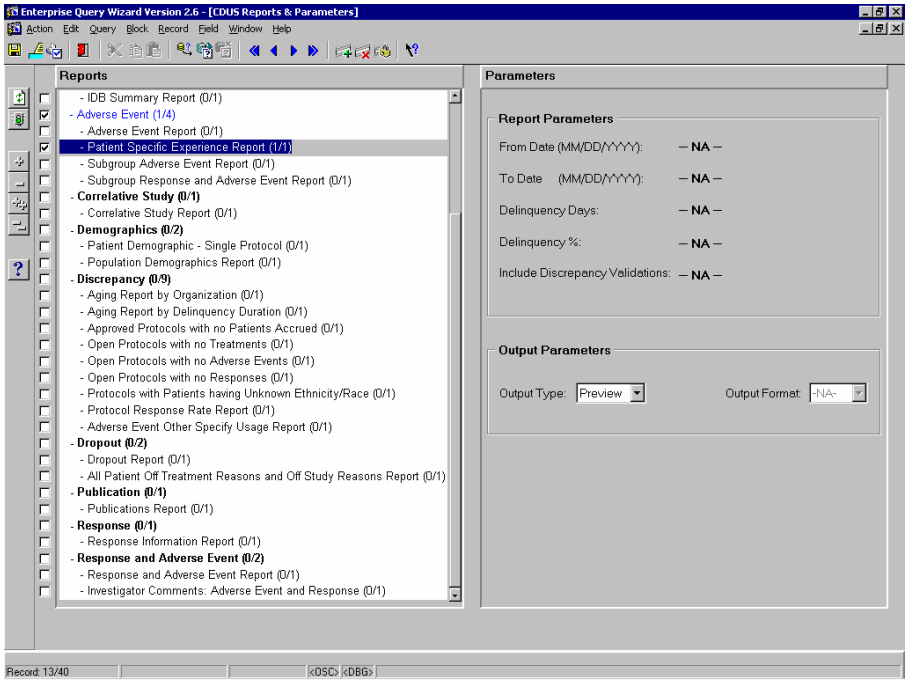


Figure 34 – Patient Specific Experience Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Lead Organization:** The lead organization for the protocol + "/" + the principal investigator for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.

- **Cutoff Date:** The most recent date for which any data was used in compiling results. This date should reflect the latest date for which information is known. (MM/DD/YYYYY).
- **Patients Registered/Patients Treated:** The total number of patients who have registered for this protocol /patients who had at least one treatment course on this protocol.
- **Activation Date:** The activation date for the protocol as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Planned Accrual:** The planned range of patient accrual. The min accrual + " –"+ the max accrual is displayed as entered in PATS.
- **Prior Therapy Eligibility Criteria:** The prior therapy eligibility criteria for the protocol as entered in PATS. If no record is found then the text "N/A" is displayed.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Disease:** The lead disease being studied on the protocol as entered in PATS.
- **Grant:** The grant(s) on the protocol as entered in PATS.
- **Median # Courses/Patient:** The median total number of courses across all patients.
- **Lead Agent, NSC:** The NSC + "," + NAME for the lead NSC for the protocol as entered in PATS.
- **Total # Courses for all Patients:** The total number of courses for all patients on the protocol.
- **Patient ID:** The patient's SOURCE_PATIENT_ID as submitted using CDUS.
- **Registering Institute:** Name of a specified organization.
- **Date of Entry:** The date (MM/DD/YYYY) the patient entered the study. CTEP recommends using the date the patient was registered on the trial or study.
- **Best Response:** The patient's BEST_RESPONSE as submitted using CDUS. The best response is the response which has the highest order in the response sequence: Complete Response>Partial Responses>Less than Partial

Response>Stable>Progression>Not assessed adequately > Other.

- **Treatment Assignments:** TRT_ASGNMT_CODE + " –" + DESCRIPTION

  The treatment assignments are displayed in ascending order of Treatment Assignment code.

- **Course Date:** The date the patient began on the treatment course.

- **Grade:** Defines the levels of adverse reaction to a treatment, based on clinical criteria, ranging from 0,representing no toxicity or response within normal limits, to 5, representing death related to toxicity.

- **Attribution:** The Adverse Event Attribution Identification number defining the likelihood that the IND of the treatment course assigned to a patient being the cause of the adverse event.

Business Rules

The following business rules determine the report's output.

- **Cutoff Date:** This date should reflect the latest date for which information is known. (MM/DD/YYYYY).

- **Prior Therapy Eligibility Criteria:** If no record is found then the text "N/A" is displayed.

- **Date of Entry:** The date (MM/DD/YYYY) the patient entered the study. CTEP recommends using the date the patient was registered on the trial or study.

- **Best Response:** The best response is the response which has the highest order in the response sequence: Complete Response>Partial Responses>Less than Partial Response>Stable>Progression>Not assessed adequately > Other.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- Baseline Abnormalities information now displays before the actual treatment and toxicity from the baseline abnormalities table. The following columns are displayed:
  - Adverse Event
  - Grade

- Late Adverse Event information now is displayed after the actual treatment and toxicity from the off treatment events table. The following columns are displayed:
  - Adverse Event
  - Grade
  - Start Date Start date of the adverse event.
- The off study date and reason from the patients table is now displayed.
- If there are treatments reported on a protocol but not toxicities, the report displays the treatment assignment code and under toxicities "—No Toxicities Reported—."
- The patient's Disease Type now is included.
- If the Adverse Event type is other, the AE_Other_Specify is displayed.
- If no treatment assignment code is attached to a treatment course, then under the column 'Treatment Assignment/Description" the report displays 'Treatment NOS' along with the course start date and its toxicities.
- The response for the patient is displayed after the actual treatment and toxicity. The responses are displayed in descending order by observed date. The following columns are displayed:
  - Category Response category.
  - Observed Date Date when the response was observed.

With CDUS Report Writer version 4.0 and future releases, the report displays the CTCAE version at the top of the report along with the Protocol Number and Title for a study. The Adverse Event information is displayed as a concatenation of the Adverse Event and Select AE. In addition, the baseline performance status is displayed in the Patient block.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Patient Specific Experience Report

Date: 04/09/2004

CALGB-99903-A Phase II Study of Arsenic Trioxide (NSC #706363, IND #57974) in Urothelial Cancer

Lead Organization/PI:	Cancer and Leukemia Group B / Dean F. Bajorin			**CTCAE Version:**	2.0
Current Status, Status Date:	Closed to Accrual, 03/15/2002	**Cutoff Date:**	09/30/2003	**Patients Registered / Treated/On Study :**	13 / 12 / 0
Activation Date:	12/15/2000	**Monitoring Method:**	CDUS - Complete	**Planned Accrual:**	12-35
Prior Therapy (Eligibility Criteria):	One prior treatment regimen, which must have included one of the following chemotherapy agents: cisplatin, carboplatin, paclitaxel, or gemcitabine. > or = 4 weeks since prior RT or CT.				
Lead IND:	57974	**NSC, Lead Agent:**	706363, ARSENIC TRIOXIDE (Trisenox)	**Lead Disease:**	Bladder neoplasm NOS
Median # Courses/Patients:	2	**Funding Information:**	U10 CA 31946	**Total # Courses (for all patients):**	28

Patient ID:	84753	**Registering Institution:**	Memorial Sloan Kettering Cancer Ctr	**Date of Entry:**	03/23/2001
Best Response (Date):	Stable (05/10/2001)	**Off Study Reason & Date (if applicable):**	Death 11/09/2001		
Subgroup:	SG1 - All Patients	**Disease:**	N/A	**Performance Staus:**	

Baseline Abnormalities

AE Reported by Grade	Grade 1	2	3	4	5
-- No Baseline Abnormalities Reported --					

Treatment Assignment Code/Description	Course Date	AE Reported By Grade	Grade 1	2	3	4	5	Attribution	AER Flag	Date Expedited
TA1 / ARSENIC TRIOXIDE 0.3mg/KG IV over 1 hour daily for 5 day(s) every 28 days.	03/26/2001	Anorexia	1					Possible	Yes	
		Diarrhea patients without colostomy		1				Possible	Yes	
		Edema		1				Possible	Yes	
		Fatigue (lethargy, malaise, asthenia)		1				Possible	Yes	
		Hemoglobin	1					Probable	Yes	
		Leukocytes (total WBC)		1				Probable	Yes	
		Nausea		1				Possible	Yes	
		Neutrophils/granulocytes (ANC/AGC)			1			Possible	Yes	
		Prothrombin time (PT)			1			Unlikely	Yes	
		SGPT (ALT) (serum glutamic pyruvic transaminase)	1					Possible	Yes	
		Thrombosis/embolism				1		Unrelated	Yes	

Page 2 of 15

Figure 35 – Sample Patient Specific Experience Report

The Subgroup Adverse Event Report

This report summarizes by subgroup the total number of patients, total number of treatment courses, and the total number of treatment courses for which toxicity has been reported.

Running the Report

1. Click the checkbox to the left of **Subgroup Adverse Event Report**.

Parameters appear in the right frame as shown in Figure 36.

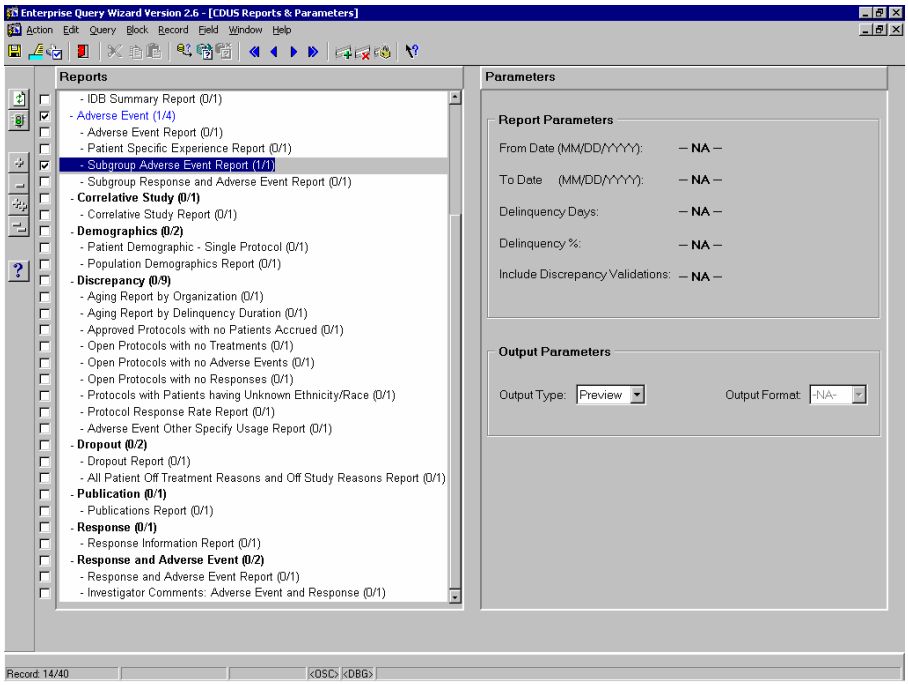


Figure 36 – Subgroup Adverse Event Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Treatment Assignments:**

The treatment assignments are displayed in ascending order by DOSE_LEVEL_ORDER. A secondary sort is on Treatment Assignment code. Only those treatment assignments for which there are data are displayed. If there are no patients entered on a treatment assignment,

then that treatment assignment will be left off of the report.

- **Subgroup Code:** Information on how patients in a protocol are uniformly grouped for analysis or treatment. These groupings are usually based on protocol stratification criteria, e.g., age, prior therapies, disease and/or node+/-.

- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type; only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

- **X esc from Y**: The count (**X esc from Y**) is the number of patients who escalated from treatment assignment Y to the current treatment assignment.

- **A Deesc from B:** The count (**A Deesc from B**) is the number of patients who de-escalated from treatment assignment B to the current treatment assignment.

- **The count Z pt. for course 1:** The count **Z pt.** in the course 1 column for a treatment assignment is the number of patients who had toxicities associated with the course (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) that had the minimum COURSE_START_DATE on that treatment assignment.

- **The count Z pt. for course 2+:** The count Z pt. in the course 2+ signifies the number of patients who had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course except the one with the minimum COURSE_START_DATE associated with it.

  It also signifies those who had the current treatment assignment on their maximum COURSE_START_DATE and the maximum COURSE_START_DATE is not equal to the minimum COURSE_START_DATE.

- **The count (n= X) for course 1:** The counts **n = X** for course 1 is the sum of the Z pt. counts for all the treatment assignments for course 1.

  Therefore, this is a count of all patients who

had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) during their first course of treatment.

- **The count (n= X) for course 2+:** The counts **n = X** for course 2+ is the sum of the Z pt. counts for all the treatment assignments for course 2+.

  Therefore, this is a count of all patients who had toxicity (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course other than their first course of treatment.

- **# started in:** The number of patients who had the course with the minimum COURSE_START_DATE lying in the current treatment assignment.

- **# escalated to:** The number of patients escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

- **Phase:** The phase for the protocol.
- **Lead Organization:** The active lead organization for the protocol + "/ " + the principal investigator for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Activation Date:** The activation date for the protocol as entered in PATS.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered on the protocol.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Planned Accrual:** The planned range of patient accrual. The minimum accrual + "-" + the maximum accrual is displayed as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Prior Therapy Eligibility Criteria:** The prior therapy eligibility criteria for the protocol as entered in PATS.

  If no record is found then the text "N/A" is displayed.

- **Dose Limiting Toxicities:** Dose limiting toxicities for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.
- **Recommended Phase II Dose:** Recommended phase II dose for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.
- **IND:** The lead IND number for the protocol.
- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol.
- **Total # Courses for all Patients:** The total number of courses for all patients on the protocol.
- **Median # Courses/Patient:** The median total number of courses across all patients.
- **Range # Courses/Patient:** The minimum and maximum number of treatment courses received by a patient.

Business Rules

The following business rules determine the report's output:

- **Treatment Assignments:** If there are no patients entered on a treatment assignment, then that treatment assignment will be left off of the report.
- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type, only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

  If the toxicity is associated with the course having the patient's minimum COURSE_START_DATE, then it is displayed under column **Course 1**, otherwise it is displayed under the column **Course 2+**. Toxicities of Grade 1, 2, and 3 with an attribution of "unrelated" or "unlikely" will not be included in the report.
- **X esc from Y**: The count (**X esc from Y** is based on the following logic:

  A patient is escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum

COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

- **A Deesc from B:** The count (**A Deesc from B**) is based on the logic that a patient is de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.
- **Prior Therapy Eligibility Criteria:** If no record is found then the text "N/A" is displayed.
- **Dose Limiting Toxicities:** If no record is found then the text "Not Reported" is displayed.
- **Recommended Phase II Dose:** If no record is found then the text "Not Reported" is displayed.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- The count of patients for each subgroup under that treatment is displayed.
- The status date of the protocol is displayed.
- If the Adverse Event type is other, the AE_Other_Specify is displayed.
- Below the treatment assignment, the following is displayed:
  - **# experiencing AE:** The number of patients in the current treatment assignment that have AE experienced = 'Yes.'
  - **# de-escalated to:** The number of patients de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.
  - **# treated:** The number of patients lying in the current treatment assignment.

- **# dose change:** The number of patients lying in the current treatment assignment and had a dose change flag of either 'Yes, planned' or 'Yes, unplanned.'

With CDUS Report Writer version 4.0 and future releases, the report displays the CTCAE version at the top of the report along with the Protocol Number and Title for a study. The Adverse Event information is displayed as a concatenation of the Adverse Event and Select AE.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Clinical Trial Summary: Subgroup Adverse Event Report

Date : 02/16/2005

CALGB-99903 - A Phase II Study of Arsenic Trioxide (NSC #706363, IND #57974) in Urothelial Cancer

Phase: II
CTCAE Version: 2.0
Lead Organization/PI: Cancer and Leukemia Group B / Dean F. Bajorin
Current Status/Date: Closed to Accrual / 03/15/2002
Patients Registered/Treated/On Study: 13 / 12 / 0
Activation Date: 12/15/2000
Planned Accrual: 12 - 35
Cutoff Date: 09/30/2003
Monitoring Method: CDUS - Complete
Dose Limiting Adverse Events: Not Reported
Recommended Phase II Dose: Not Reported
Lead IND: 57974
NSC: 706363 ,ARSENIC TRIOXIDE (Trisenox)
Total # of Courses (for all patients): 28
Median # of Courses (per patient): 2
Range # of Courses (per patient): 1-8

Treatment Assignment

TA1 : ARSENIC TRIOXIDE
0.3mg/KG IV over 1 hour daily for 5 day(s) every 28 days.

 # experiencing AE: 11
 # started in: 12
 # escalated to: 0
 # de-escalated to: 0
 # treated: 12
 # dose change: 3

Subgroup (1 pt.) SG1 : All Patients		AE Reported Course 1 (n=10)** Grade: 1	2	3	4	5	AE Reported Course 2+ (n=2)** Grade: 1	2	3	4	5
		10 pts.					2 pts.				
ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	1									
BLOOD/BONE MARROW	Hemoglobin	2	3	1				1			
	Leukocytes (total WBC)	1	1					1			
	Lymphopenia		1								
	Neutrophils/granulocytes (ANC/AGC)		1	1				1			
	Platelets	1	1								
CARDIOVASCULAR (ARRHYTHMIA)	Palpitations	1									
CARDIOVASCULAR (GENERAL)	Edema	4	1				1				
	Hypotension		1								

** This report includes grade 3, 4 and 5 events regardless of attribution and grades 1 and 2 events with a possible to definite attribution.

Figure 37 – Sample Subgroup Adverse Event Report

The Subgroup Response and Adverse Event Report

This report summarizes by subgroup the total number of patients, total number of treatment courses, and the total number of treatment courses for which toxicity has been reported.

Running the Report

1. Click the checkbox to the left of **Subgroup Response and Adverse Event Report**.

Parameters appear in the right frame as shown in Figure 38.

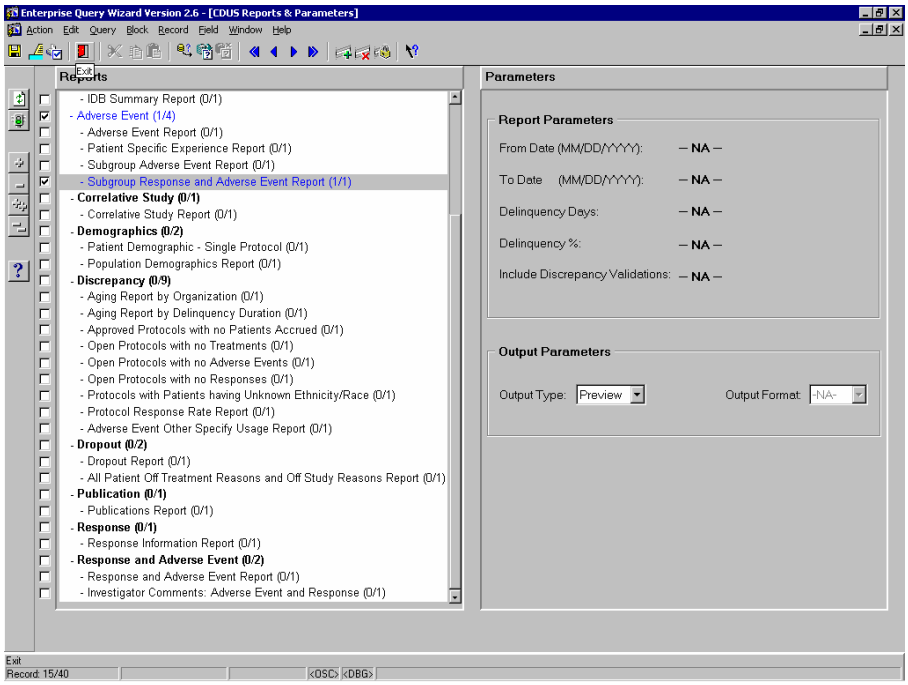


Figure 38 – Subgroup Response and Adverse Event Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Phase:** The phase for the protocol.
- **Lead Organization:** The active lead organization for the protocol + "/ " + the principal investigator for the protocol as entered in PATS.

- **Current Status:** The current status of the protocol as entered in PATS.
- **Activation Date:** The activation date for the protocol as entered in PATS.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered on the protocol.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Planned Accrual:** The planned range of patient accrual. The minimum accrual + "-" + the maximum accrual is displayed as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Prior Therapy Eligibility Criteria:** The prior therapy eligibility criteria for the protocol as entered in PATS.

  If no record is found then the text "N/A" is displayed.
- **Dose Limiting Toxicities:** Dose limiting toxicities for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.
- **Recommended Phase II Dose:** Recommended phase II dose for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.
- **IND:** The lead IND number for the protocol.
- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol.
- **Total # Courses for all Patients:** The total number of courses for all patients on the protocol.
- **Median # Courses/Patient:** The median total number of courses across all patients.
- **Range # Courses/Patient:** The minimum and maximum number of treatment courses received by a patient.
- **Subgroup Code:** Information on how patients in a protocol are uniformly grouped for analysis or treatment. These groupings are usually based on protocol stratification criteria, e.g., age, prior therapies, disease and/or node+/-.
- **Treatment Assignments:** The treatment assignments are displayed in ascending order by DOSE_LEVEL_ORDER. A secondary sort is on Treatment Assignment code. This column is displayed based on the treatments given to a patient on the subgroup displayed on the first column. If there are no patients entered on a treatment assignment,

then that treatment assignment will be left off of the report.

- **Eval . for Response:** Total number of patients who are evaluable for response as submitted using CDUS.

- **CR (Complete Response):** Counts of only those patients who have the best response as 'Complete Response' for that subgroup and treatment assignment.

- **PR (Partial Response):** Counts of only those patients who have the best response as 'Partial Response' for that subgroup and treatment assignment.

- **RR (Response Ratio):** The value displayed is based upon the formula RR = [(CR + PR) / Number of patients evaluated for response] *100

- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type; only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

- **X esc from Y**: The count (**X esc from Y**) is the number of patients who escalated from treatment assignment Y to the current treatment assignment.

- **A Deesc from B:** The count (**A Deesc from B**) is the number of patients who de-escalated from treatment assignment B to the current treatment assignment.

- **The count Z pt. for course 1:** The count **Z pt.** in the course 1 column for a treatment assignment is the number of patients who had toxicities associated with the course (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) that had the minimum COURSE_START_DATE on that treatment assignment.

- **The count Z pt. for course 2+:** The count Z pt. in the course 2+ signifies the number of patients who had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course except the one with the minimum COURSE_START_DATE associated with it.

  It also signifies those who had the current

treatment assignment on their maximum COURSE_START_DATE and the maximum COURSE_START_DATE is not equal to the minimum COURSE_START_DATE.

- **The count (n= X) for course 1:** The counts **n = X** for course 1 is the sum of the Z pt. counts for all the treatment assignments for course 1.

  Therefore, this is a count of all patients who had toxicity (Other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) during their first course of treatment.

- **The count (n= X) for course 2+:** The counts **n = X** for course 2+ is the sum of the Z pt. counts for all the treatment assignments for course 2+.

  Therefore, this is a count of all patients who had toxicity (that was other than Grade 1, 2, or 3 with an attribution of unrelated or unlikely) on any course other than their first course of treatment.

- **# started in:** The number of patients who had the course with the minimum COURSE_START_DATE lying in the current treatment assignment.

- **# escalated to:** The number of patients escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

Business Rules

The following business rules determine the report's output:

- **Treatment Assignments:** If there are no patients entered on a treatment assignment, then that treatment assignment will be left off of the report.

- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and the grade represents the count of toxicities reported for that toxicity and grade.

  In the column **Course 2+**, for a given toxicity type, only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th

course, then it would be counted once under Grade 3 Hematology.

If the toxicity is associated with the course having the patient's minimum COURSE_START_DATE, then it is displayed under column **Course 1**, otherwise it is displayed under the column **Course 2+**. Toxicities of Grade 1, 2, and 3 with an attribution of "unrelated" or "unlikely" will not be included in the report.

- **X esc from Y**:

The count (**X esc from Y** is based on the following logic:

A patient is escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.

- **A Deesc from B:**

The count (**A Deesc from B**) is based on the logic that a patient is de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.

- **Prior Therapy Eligibility Criteria:**

If no record is found then the text "N/A" is displayed.

- **Dose Limiting Toxicities:**

If no record is found then the text "Not Reported" is displayed.

- **Recommended Phase II Dose:**

If no record is found then the text "Not Reported" is displayed.

- **CR (Complete Response):**

The CR response will be attributed to the treatment assignment only if:

- It is only the treatment taken by the patient.
- The response observed date is between the 3 days after including the treatment start date and 3 days after the next treatment started. For example, Patient PAT1 started on TAC0 on 12/01/2001, TAC1 on 01/01/2002 and was moved to TAC2 on 03/01/2002. A PR was observed on 03/02/2002 and CR was observed

03/5/2003. The PR will be attributed to the TAC1, CR will be attributed to TAC2. No responses will be attributed to TAC0.
- The response observed 3 days after the last treatment will be attributed to the last treatment.
- The response observed date lies between a two treatment assignment then the response is attributed to the previous treatment assignment.

- **PR (Partial Response):** The PR response will be attributed to the treatment assignment only if:
  - It is only the treatment taken by the patient.
  - The response observed date is between the 3 days after including the treatment start date and 3 days after the next treatment started. For example, Patient PAT1 started on TAC0 on 12/01/2001, TAC1 on 01/01/2002 and was moved to TAC2 on 03/01/2002. A PR was observed on 03/02/2002 and CR was observed 03/5/2003. The PR will be attributed to the TAC1, CR will be attributed to TAC2. No responses will be attributed to TAC0.
  - The response observed 3 days after the last treatment will be attributed to the last treatment.
  - The response observed date lies between a two treatment assignment then the response is attributed to the previous treatment assignment.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- The count of patients for each subgroup under that treatment is displayed.
- The status date of the protocol is displayed.
- If the Adverse Event type is other, the AE_Other_Specify is displayed.
- Below the treatment assignment, the following is displayed:
  - **# experiencing AE:** The number of patients in the current treatment assignment that have AE experienced = 'Yes.'
  - **# de-escalated to:** The number of patients de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for

that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's DOSE_LEVEL_ORDER.

- **# treated:** The number of patients lying in the current treatment assignment.
- **# dose change:** The number of patients lying in the current treatment assignment and had a dose change flag of either 'Yes, planned' or 'Yes, unplanned.'

With CDUS Report Writer version 4.0 and future releases, the report displays the CTCAE version at the top of the report along with the Protocol Number and Title for a study. The Adverse Event information is displayed as a concatenation of the Adverse Event and Select AE.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Clinical Trial Summary: Subgroup Response and Adverse Event Report

Date : 02/16/2005

T99-0010 - A Phase II Study of Oxaliplatin in Combination with Fluorouracil and Leucovorin and Carcinoma of the Esophagus and Gastric Cardia

Phase: II
CTCAE Version: 2.0
Lead Organization/PI: University of Chicago / Ann M. Mauer
Current Status/Date: Administratively Complete / 02/21/2003
Patients Registered/Treated/On Study: 35 / 35 / 0
Activation Date: 12/07/1999
Planned Accrual: 12 - 37
Cutoff Date: 12/31/2002
Monitoring Method: CDUS - Complete
Dose Limiting Adverse Events: Not Reported
Recommended Phase II Dose: Not Reported
Lead IND: 57004
NSC: 19893, 5-FLUOROURACIL
266046, OXALIPLATIN
3590, CALCIUM LEUCOVORIN
Total # of Courses (for all patients): 323
Median # of Courses (per patient): 7
Range # of Courses (per patient): 1-27

Subgroup	Treatment Assignment		AE Reported (All Courses)**				
		Grade:	1	2	3	4	5
SG110015 35 pts.	TA110015						
Response	**CR** 1 **PR** 13						
Eval 34	**# Experiencing AE** 35	ALLERGY/IMMUNOLOGY					
CR 1	**# started in:** 35		Allergic reaction/hypersensitivity (including drug fever)	1	1		1
PR 13	**# Esc. to:** 0		Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	2			
RR(%) 41.2	**# de-esc. to:** 0	BLOOD/BONE MARROW	Hemoglobin	17	9	3	
	# treated: 35		Hemolysis (e.g., immune hemolytic anemia, drug related hemolysis, other)	1			
	# dose change: 0		Leukocytes (total WBC)	6	14	7	1
			Lymphopenia	2	3	5	
			Neutrophils/granulocytes (ANC/AGC)	2	3	12	11
			Platelets	14	2	2	1
		CARDIOVASCULAR (ARRHYTHMIA)	Sinus tachycardia	1			

** This report includes grade 3, 4 and 5 events regardless of attribution and grades 1 and 2 events with a possible to definite attribution.

Figure 39 – Sample Subgroup Response and Adverse Event Report

The Correlative Study Report

This report provides information about correlative studies associated with the protocol. It displays the parameter values selected for the original query.

Running the Report

1. Click the checkbox to the left of **Correlative Study Report**.

Parameters appear in the right frame as shown in Figure 40.

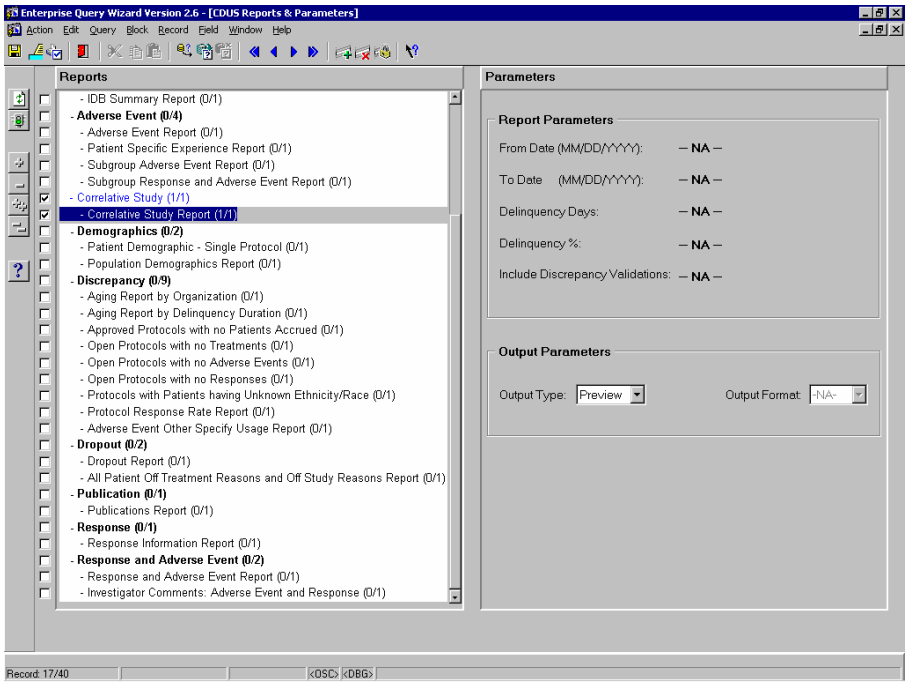


Figure 40 - Correlative Study Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Phase:** The phase for the protocol.
- **Lead Organization:** The lead organization for the protocol + "/ " + the principal investigator for the protocol as entered in PATS.
- **Current Status , Status Date:** The current status of the protocol + " , " + the current status date for the protocol as entered in PATS.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Lead NSC:** The NSC + " , " + NAME for the lead NSC for the protocol as entered in PATS.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Correlative Study Title:** The title of the study as provided by the investigators in the Protocol Submission Checklist.
- **Patients Collected:** The total number of patients collected.
- **Patients Analyzed:** The total number of patients analyzed.
- **Findings or Conclusions:** A brief summary reporting the findings or conclusions of the study.
- **Cutoff Date:** The most recent date for which any data was used in compiling results. This date should reflect the latest date for which information is known. (YYYYMMDD).

Business Rules

Business rules do not govern the results of this report.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- These columns have been added:
  - Samples Collected Total number of samples collected.

- Samples Analyzed Total number of samples analyzed.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Correlative Study Findings Report

Date : 04/09/2004

T99-0003 - A Phase I Study of Oxaliplatin in Combination with Gemcitabine

Phase: I **Lead Organization/PI:** City of Hope Medical Center / Stephen I. Shibata **Current Status, Status Date:** Administratively Complete, 02/21/2003

Lead IND#: 57004 **Lead NSC#:** 266046, OXALIPLATIN **Patients Treated:** 43 **Cutoff Date:** 06/30/2003

Correlative Study Title	# Patients		# Samples		Findings or Conclusions
	Collected	Analyzed	Collected	Analyzed	
Oxaliplatin-DNA adducts	0	0	0	0	
Oxaliplatin pharmacokinetics	1	0	15	0	
gemcitabine pharmacokinetics	1	0	7	0	
HER-2/neu oncogene protein staining by immunohistochemistry	0	0	0	0	
Ras mutational status by PCR	0	0	0	0	
Deoxycitidine deaminase mRNA by RT-PCR	0	0	0	0	
Ribonucleotide reductase mRNA by RT-PCR	0	0	0	0	
bax mRNA by RT-PCR	0	0	0	0	
hMSH1 mRNA by RT-PCR	0	0	0	0	
ERCC1 m RNA by RT-PCR	0	0	0	0	
Deoxycidine kinase mRNA by RT-PCR	0	0	0	0	
hMSH2 mRNA by RT-PCR	0	0	0	0	
Heat shock protein 70 mRNA by RT-PCR	0	0	0	0	
bcl2 mRNA by RT-PCR	0	0	0	0	

Figure 41 – Sample Correlative Study Report

The Demographics Reports

The Patient Demographics - Single Protocol Report

This report provides demographic information on the patients participating in a protocol. All data is queried directly from the PATIENTS table.

The following administrative data is displayed at the top of every report:

- Protocol Number
- Cutoff Date
- Trial Phase Code
- Monitoring Code
- Title
- Lead Disease
- Funding Information
- Study Disease Classification (abstracted for the protocol)

Running the Report

1. Click the checkbox to the left of **Patient Demographics**.

Parameters appear in the right frame as shown Figure 42.

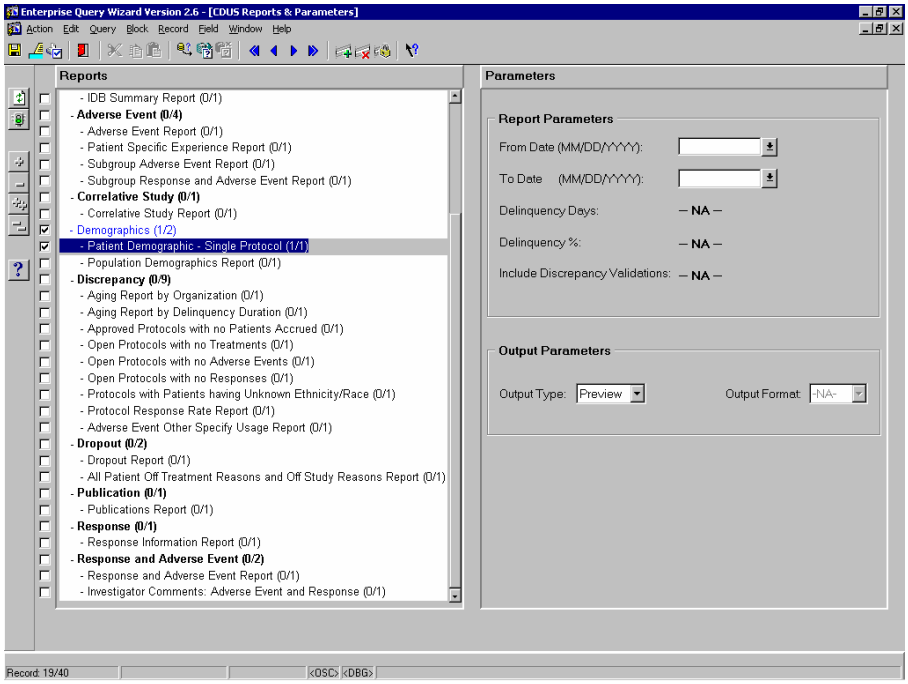


Figure 42 -Patient Demographics Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

The information reported for each patient is as follows:

- **Patient ID:** Patient's unique identification number within the study.
- **Disease:** Disease Name in Simplified Disease Classification terms. If the study is assigned to MedDRAv6.0, the title for this column is Disease**, where ** denotes the following footnote:

  "** - Protocols approved prior to 10/1/2004 and not requesting to submit Simplified Disease Classification will have the CTEP 'Recommended' term(s) displayed. The Study Disease Classification for these protocols is MedDRAv6.0. Contact NCI CTEP Help Desk

for assistance."

- **Date of Birth:** Patient's birth date.
- **Gender:** Patient's gender.
- **Race:** Patient's race.
- **Ethnicity:** Ethnicity of the patient.
- **Method of Payment:** Patient's primary method of payment.
- **Date of Entry:** Date the patient entered the study.
- **Registering Group:** CTEP Group code where the patient was originally registered.
- **Registering Institution:** The CTEP institution where the patient was originally registered (signed the informed consent).

Business Rules

Business rules do not determine this report's output.

Enhancements

With CDUS Report Writer version 3.0 and future releases, the report displays Race and Ethnicity as separate columns. If a patient has multiple races, then all races for the patient are displayed.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Patient Demographic Report - Single Protocol

Date : 03/23/2005
Page : 2 of 3

NCI Protocol # : T98-0011
Cutoff Date : 09/30/2003
Trial Phase Code : II
Monitoring Code : CDUS - Abbreviated
Title : A Phase II trial of intravenous cereport(rmp-7) and carboplatin in childhood brain tumors
Lead Disease : Anaplastic astrocytoma
Funding Information: U10 CA 98543
Study Disease Classification: SDCv1.0

Patient ID	Disease	Date of Birth	Gender	Race	Ethnicity	Method of Payment	Date of Entry	Registering* Group	Registering Institution
AD, DC-032		03/1981	Female	White	Not Hispanic or Latino	Private Insurance	09/11/2000	Children's Cancer Group	Childrens National Medical Center
AN, ST-029		08/1985	Male	White	Not Hispanic or Latino	Private Insurance	05/30/2000	Children's Cancer Group	Children's Hospital and Regional Medical Center
BN, ST-024		06/1984	Male	White	Not Hispanic or Latino	Unknown	01/10/2000	Children's Cancer Group	Children's Hospital and Regional Medical Center
BT, ST-039		12/1994	Male	Unknown	Unknown	Medicaid	09/07/2001	Children's Oncology Group	Children's Hospital and Regional Medical Center
EL, HT-028		07/1982	Female	Unknown	Hispanic or Latino	Private Insurance	04/18/2000	Children's Cancer Group	M.D. Anderson Cancer Center
EL, SF-026		12/1988	Male	White	Not Hispanic or Latino	Private Insurance	02/02/2000	Children's Cancer Group	University of California San Francisco Medical Center
IK, DC-035		08/1988	Female	White	Not Hispanic or Latino	Private Insurance	12/04/2000	Children's Cancer Group	Childrens National Medical Center
JH, DC-025		09/1992	Male	White	Not Hispanic or Latino	Private Insurance	01/27/2000	Children's Cancer Group	Childrens National Medical Center
JS, PB-040	Medulloblastoma	05/1992	Male	White	Not Hispanic or Latino	Other	12/20/2001		National Cancer Institute Pediatric Oncology Branch
KB,PB-041		03/1981	Female	White	Not Hispanic or Latino	Other	09/19/2002		National Cancer Institute Pediatric Oncology Branch
KM, NY-034		07/1996	Male	Unknown	Unknown	Private Insurance	11/20/2000	Children's Cancer Group	Beth Israel Medical Center

* Only for intergroup studies

** - Protocols approved prior to 10/1/2004 and not requesting to submit Simplified Disease Classification will have the CTEP 'Recommended' term(s) displayed. The Study Disease Classification for these protocols is MedDRAv6.0. Contact NCI CTEP Help Desk for further assistance.

Figure 43 – Sample Patient Demographics - Single Protocol Report

The Population - Demographics Report

The Population Demographics report provides the total accrual by Age, Race and Gender across multiple studies. The report includes a summary page with sections for Accrual by Age, Accrual by Race, Accrual by Ethnicity, Accrual by Gender, and Accrual by Disease.

Running the Report

1. Click the checkbox to the left of **Population Demographics**.

Parameters appear in the right frame as shown Figure 44.

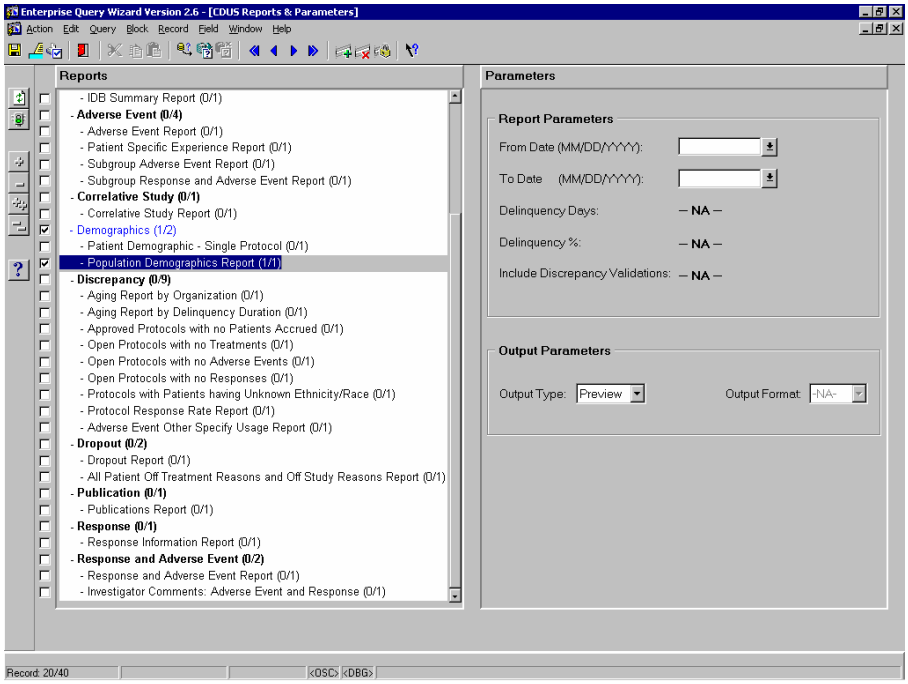


Figure 44 -Population Demographics Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

- **Protocol Number:** The unique identifier for a document.

- **Phase:** The Phase of the protocol.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Lead Organization:** The active lead organization for the protocol.
- **Lead NSC#:** The lead NSC for the protocol as entered in PATS.
- **Lead Agent:** The lead Agent NAME for all the NSCs for the protocol as entered in PATS.
- **Lead IND#:** The lead IND number for the protocol as entered in PATS.
- **Study Disease Classification** The Study Disease Classification abstracted for the protocol.
- **Lead Disease:** The lead disease(s) being studied on the protocol as entered in PATS.

Accrual by Age (Age is calculated based on Date of entry and not System date)

- **< 1 Month** Number of patients accrued on study whose age is less than 1 month.
- **> 1 month - < 2 yrs** Number of patients whose age is between 1 month and 2yrs.
- **> 2 yrs - < 12 yrs** Number of patients whose age is greater than 2 yrs and less than 12 yrs.
- **>12 yrs - < 16 yrs** Number of patients accrued on study whose age is greater than 12 yrs and less than 16 yrs.
- **> 16 yrs - < 18 yrs** Number of patients accrued on study that are more than 16 yrs of age and less than 18 yrs of age.
- **> 18 yrs - < 65 yrs** Number of patients accrued on study that are more than 18 yrs of age and less than 65 yrs of age.
- **> 65 yrs** Number of patients accrued on study who are more than 65 yrs of age.
- **Unknown** Number of patients accrued on study whose age is unknown.

Accrual by Race

- **White** Number of patients accrued on study whose race is defined as “White.”
- **More than one Race** Number of patients accrued on study who are of more than one race.
- **Black or African American** Number of patients accrued on study whose race is defined as “Black” or “African American.”
- **Native Hawaiian or other Pacific Islander** Number of patients accrued on study whose race is defined as Native Hawaiian or other Pacific Islander.

- **Asian** — Number of Asian patients accrued on study.
- **American Indian or Alaska Native** — Number of patients accrued on study who are either American Indians or Alaska Native.
- **Not Reported** — Number of patients on accrued on a study with ethnicity not reported.
- **Unknown** — Number of patients accrued on study with Race defined as "Unknown."

Accrual by Ethnicity

- **Hispanic or Latino** — Number of patients whose ethnicity is defined as "Hispanic or Latino."
- **Not Hispanic or Latino** — Number of patients whose ethnicity is defined as "Not Hispanic or Latino."
- **Not Reported** — Number of patients on accrued on a study with ethnicity not reported.
- **Unknown** — Number of patients accrued on study with ethnicity defined as "Unknown."

Accrual by Gender

- **Male** — Number of male patients accrued on study.
- **Female** — Number of female patients accrued on study.
- **Unknown** — Number of patients accrued on study whose gender is unknown.

Accrual by Disease

- **Diseases Abstracted:** — This subsection lists all disease names abstracted for the study and provides both a count and a percentage of patients accrued to each disease.
- **Diseases Not Abstracted:** — This subsection lists all patient disease names submitted but not abstracted on the study and provides both the count and the percentage accrued to each disease
- **No Patient Disease Submitted:** — This subsection lists the count and percentage of patients accrued to the study with no associated disease submitted..

Other information displayed for every section:

- **Total Accrual:** — Number of patients accrued for the study.
- **Age Range:** — The Age range of patients accrued on the study (starting from the date of entry).
- **Current Status:** — The current status of the protocol as entered in PATS.
- **Status Date:** — The status date for the protocol.

- **Data Source:** The monitoring method for the protocol as entered in PATS along with the cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients (%):** (Number of Patients accrued respectively (by age/race/gender/ethnicity) / Total number of patients accrued for the current trial) * 100
- **No. of Patients:** Total number of patients accrued by age/race/gender/ethnicity on a study.

Business Rules

Age Range	When calculating this for the entire report, exclude the protocols that have an age range of 0-0.

Enhancements

With CDUS Report Writer version 4.0 release 7 and future releases, the **All Trials** field and the **Patients (%) (All Trials)** column have been replaced by a summary page.

Sample Report

A representation of this report is provided on the following pages. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Date: 03/23/2005

Population Demographics Report

Summary Patients Demographic Accrual for Selected Protocols

	No. of Pts.	Pts. (%)
Accrual by Age :		
<1 Month	0	0
>= 1 month - < 2 yrs	0	0
>= 2 yrs - <12 yrs	0	0
>=12 yrs - <16 yrs	0	0
>=16 yrs - <18 yrs	0	0
>=18 yrs - < 65 yrs	76	82.6
>=65 yrs	16	17.4
Unknown	0	0
Accrual by Race :		
White	73	79.3
More than one Race	0	0
Black or African Amer.	16	17.4
Native HI / Pacific Isl.	0	0
Asian	0	0
Amer. Ind. / AK Native	0	0
Not Reported	0	0
Unknown	3	3.3
Accrual by Ethnicity:		
Hispanic or Latino	4	4.3
Not Hispanic or Latino	87	94.6
Not Reported	0	0
Unknown	1	1.1
Accrual by Gender :		
Male	60	65.2
Female	32	34.8
Unknown	0	0
Total Accrual:	92	
Age Range:	27 - 74	

	No. of Pts.	Pts. (%)
Accrual by Disease:		
Diseases Abstracted:	44	47.8
Adenocarcinoma of the colon	44	47.8
Diseases Not Abstracted:	48	52.2
Adenocarcinoma of the rectum	4	4.3
Colorectal cancer, NOS	37	40.2
Gastric cancer, NOS	1	1.1
Gastrointestinal cancer, NOS	5	5.4
Small intestine cancer, NOS	1	1.1
No Patient Disease Submitted:	0	0

*Patient demographic information was not collected for this protocol.

**Protocols approved prior to 10/1/2004 and not requesting to submit Simple Disease Classification will have the CTEP 'Recommended' term(s) displayed. The Study Disease Classification for these protocols is MedDRAv6.0. Contact NCI CTEP Help Desk for further assistance.

Figure 45 – Sample Population - Demographics Report (page 1 of 2)

Date: 03/23/2005

Population Demographics Report

Protocol Number:	T99-0011
Phase:	I
Principal Investigator:	Eva Szabo
Lead Organization:	NCINAV - National Cancer Institute Navy Medical Oncology Branch
Lead NSC#:	266046
Lead Agent:	OXALIPLATIN
Lead IND#:	57004
Study Disease Classification:	SDCv1.0
Lead Disease:	Invasive breast carcinoma

	No. of Pts.	Pts.(%)
Accrual by Age :		
<1 Month	0	0
>= 1 month - < 2 yrs	0	0
>= 2 yrs - <12 yrs	0	0
>=12 yrs - <16 yrs	0	0
>=16 yrs - <18 yrs	0	0
>=18 yrs - < 65 yrs	76	82.6
>=65 yrs	16	17.4
Unknown	0	0
Accrual by Race		
White	73	79.3
More than one Race	0	0
Black or African Amer.	16	17.4
Native HI / Pacific Isl.	0	0
Asian	0	0
Amer. Ind. / AK Native	0	0
Not Reported	0	0
Unknown	3	3.3
Accrual by Ethnicity:		
Hispanic or Latino	4	4.3
Not Hispanic or Latino	87	94.6
Not Reported	0	0
Unknown	1	1.1
Accrual by Gender :		
Male	60	65.2
Female	32	34.8
Unknown	0	0

	No. of Pts.	Pts.(%)
Accrual by Disease:		
Diseases Abstracted:	44	47.8
Adenocarcinoma of the colon	44	47.8
Diseases Not Abstracted:	48	52.2
Adenocarcinoma of the rectum	4	4.3
Colorectal cancer, NOS	37	40.2
Gastric cancer, NOS	1	1.1
Gastrointestinal cancer, NOS	5	5.4
Small intestine cancer, NOS	1	1.1
No Patient Disease Submitted:	0	0

Total Accrual:	92
Age Range:	27 - 74
Current Status/ Date:	Closed to Accrual 06/17/2003
Data Src./ Cutoff Dt:	CDUS - Complete 09/30/2003

*Patient demographic information was not collected for this protocol.

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**Protocols approved prior to 10/1/2004 and not requesting to submit Simple Disease Classification will have the CTEP 'Recommended' term(s) displayed. The Study Disease Classification for these protocols is MedDRAv6.0. Contact NCI CTEP Help Desk for further assistance.

Figure 46 – Sample Population - Demographics Report (page 2 of 2)

The Discrepancy Reports

The Aging Report by Organization

This report lists all open protocols that were unsuccessful/never submitted during the last 3, 6, and 9 months. The report is grouped by organization first and then by delinquency duration.

Running the Report

1. Click the checkbox to the left of **Aging Report by Organization**.

   Parameters appear in the right frame as shown in Figure 47.

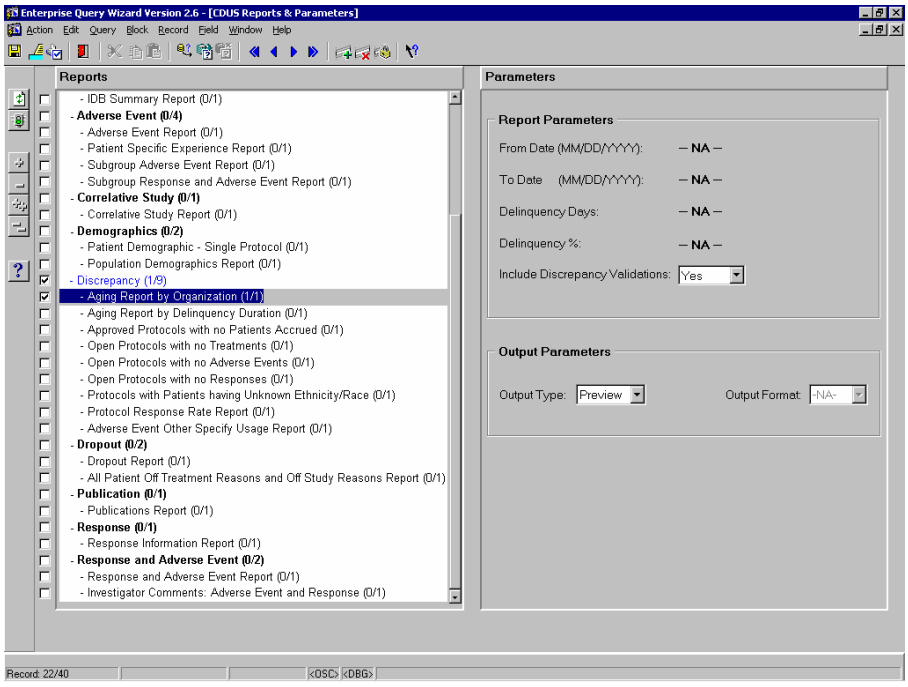

Figure 47 – Aging Report by Organization Parameters

2. Select an **Include Discrepancy Validations** parameter from the drop-down list.

Selecting “No” excludes protocols with validated discrepancies from the report. Selecting “Yes” includes all protocols with discrepancies along with any “Validation for Discrepancy” text.

3. Select **Preview** or **File** from the **Output Type** drop-down list.
4. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol’s phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol. If data was never submitted successfully, then ‘No Data Submitted’ is displayed.
- **Total Accrual**: The total number of patients accrued for the study.
- **Validation for Discrepancy** The validated and documented discrepancy.

Business Rules

The report displays the protocols based on the organization and delinquency duration. The following business rules determine the report’s output:

- **Delinquency Duration:** The delinquency durations displayed are '> 9 months,' '7–9 months,' '4–6 months' and '1–3 months.' If there are no protocols for a delinquency duration at an organization, then that delinquency duration is not displayed for that organization.

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Aging Report by Organization
(Validations for Discrepancy Included)

Date: 07/09/2004

Lead Organization : NABTT - New Approaches to Brain Tumor Therapy Consortium

Delinquency Duration : 4-6 Months

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date)	Last Successful Submission Date	Total Accrual
NABTT-2111	A Phase I/II Trial of BMS-247550 for Treatment of Patients with Recurrent High-grade Gliomas	Epothilone-B BMS 247550	Anaplastic astrocytoma	David M. Peereboom	I/II	CDUS - Complete	Active (10/18/2002)	10/30/2003	9

Validation for Discrepancy: Reason for the Discrepancy

Figure 48 – Sample Aging Report by Organization

The Aging Report by Delinquency Duration

This report lists all open protocols that were unsuccessful/never submitted during the last 3, 6, or 9 months. The report is grouped by delinquency duration first and then by organization.

Running the Report

1. Click the checkbox to the left of **Aging Report by Delinquency Duration**.

Parameters appear in the right frame as shown in Figure 49.

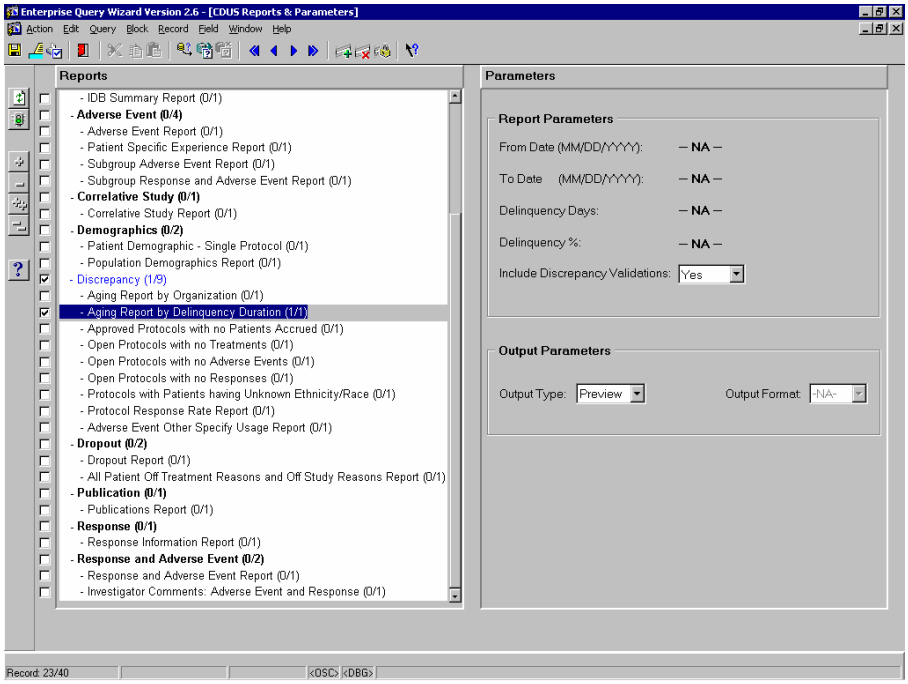

Figure 49 –Aging Report by Delinquency Duration Parameters

2. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.

3. Select **Preview** or **File** from the **Output Type** drop-down list.

4. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol. If data was never submitted successfully, then 'No Data Submitted' is displayed.
- **Total Accrual**: The total number of patients accrued for the study.
- **Validation for Discrepancy** The validated and documented discrepancy.

Business Rules

The report displays the open protocols based on the delinquency duration and organization. The following business rules determine the report's output:

- **Delinquency Duration:** The delinquency durations displayed are '> 9 months,' '7–9 months,' '4–6 months' and '1–3 months.'

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Aging Report by Delinquency Duration

Date: 07/09/2004 **(Validations for Discrepancy Included)**

Delinquency Duration : 4-6 Months

Lead Organization : NABTT - New Approaches to Brain Tumor Therapy Consortium

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date)	Last Successful Submission Date	Total Accrual
NABTT-2111	A Phase I/II Trial of BMS-247550 for Treatment of Patients with Recurrent High-grade Gliomas	Epothilone-B BMS 247550	Anaplastic astrocytoma	David M. Peereboom	I/II	CDUS - Complete	Active (10/18/2002)	10/30/2003	9
Validation for Discrepancy: Reason for the Discrepancy									

Page: 2 of 2

Figure 50 – Sample Aging Report by Delinquency Duration

The Approved Protocols with no Patients Accrued Report

This report displays all lead organizations that have protocols, where the status of the protocols is approved but no patients have been accrued. The main grouping is on the organization.

Running the Report

1. Click the checkbox to the left of **Approved Protocols with no Patients Accrued**.

Parameters appear in the right frame as shown in Figure 51.

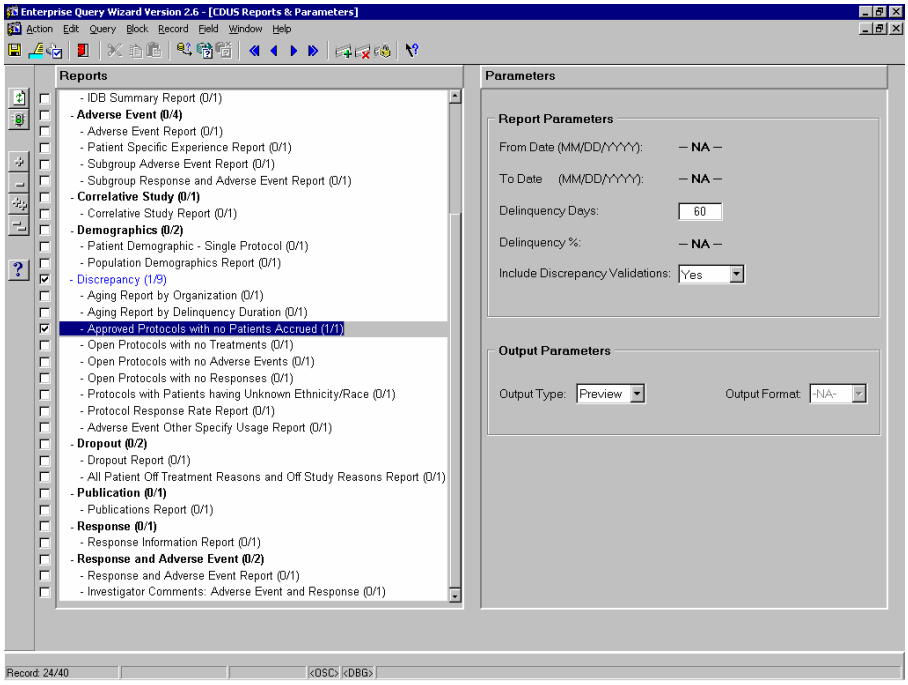

Figure 51 – Approved Protocols with no Patients Accrued Report Parameters

2. Enter the number of **Delinquency Days** up to 365. (The default is 60.)
3. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency Days (up to 365)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Planned Accrual:** The planned range of patient accrual. The min accrual + " –"+ the max accrual is displayed as entered in PATS.
- **Validation for Discrepancy** The validated and documented discrepancy.

Business Rules

The report lists all protocols that:

1. Have a status of approved or active at that organization, and
2. No patients have been accrued, and
3. Approval date of the protocol + X days should be less or equal to today's date where 'X' is a parameter defaulted to 60 and no greater than 365.

All protocols selected have the monitoring method both complete and abbreviated for CDUS and CTMS protocols.

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Approved Protocols with no Patients Accrued

Date: 07/12/2004

(60 days from Approval Date - Validations for Discrepancy Included)

Lead Organization : NCCTG - North Central Cancer Treatment Group

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	Planned Accrual
N0124	Phase II Trial of STI571 in Patients with Relapsed Small Cell Lung Cancer	STI571 (imatinib, Gleevec)	Small cell lung cancer stage unspecified	Alex A. Adjei	II	CDUS - Complete	Active (05/02/2003) (07/23/2003)	83 - 91
Validation for Discrepancy: Reason for the Discrepancy								

Page: 2 of 2

Figure 52 – Sample Approved Protocols with no Patients Accrued Report

The Open Protocols with no Treatments Report

This report displays all lead organizations that have protocols and patients accrued but no treatments reported. The information is grouped by the lead organization.

Running the Report

1. Click the checkbox to the left of **Open Protocols with no Treatments**.

Parameters appear in the right frame as shown in Figure 53.

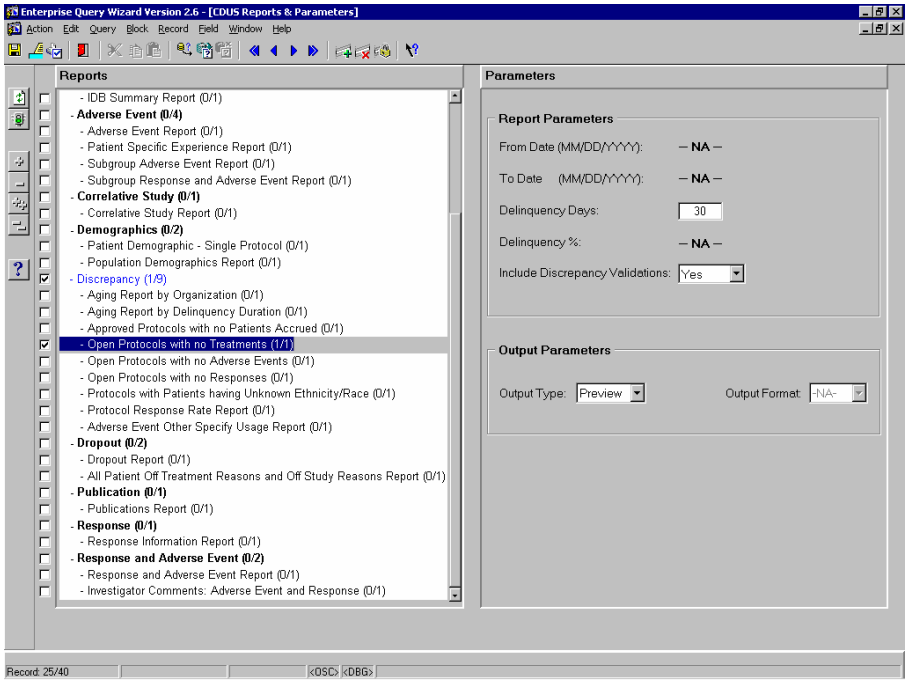

Figure 53 – Open Protocols with no Treatments Report Parameters

2. Enter the number of **Delinquency Days** up to 365. (The default is 30.)
3. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency Days (up to 365)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol.
- **No. of Patients Registered:** The total number of patients entered on the protocol.
- **No. of Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Validation for Discrepancy** The validated and documented discrepancy.
- **No. of Patients not Treated:** The total number of patients who have had no treatment courses on this protocol.
- **Patient IDs and entry dates with no treatment:** For patients with no treatment, the SOURCE_PATIENT_ID and entry date as submitted using CDUS.

Business Rules

The report lists all protocols for the organization that:

1. Have patients accrued, and
2. No treatments reported, and
3. Entry date of the protocol + X days should be less or equal to today's date where 'X' is a parameter defaulted to 30 and no greater than 365.

All protocols selected have the monitoring method ‘Complete’ for CDUS and CTMS protocols.

The report does not include protocols where all patients have Off Treatment Reason of:

- Patient withdrawal/refusal prior to beginning Protocol therapy
- Disease Progression before Active Treatment
- No treatment per protocol criteria

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Open Protocols with no Treatment

Date: 07/12/2004

(30 days from Patient Date of Entry - Validations for Discrepancy Included)

Lead Organization : TX035 - M.D. Anderson Cancer Center

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	No. Patients Reg./Treated
1652	A Phase II Study of Oxaliplatin in Relapsed and Refractory Non-Hodgkin's Lymphoma	OXALIPLATIN	NonHodgkin's lymphoma NOS refractory	Anas Younes	II	CDUS - Complete	Closed to Accrual (11/11/2003) (08/15/2003)	29 / 25
Validation for Discrepancy: Reason for the Discrepancy								
No. of Patients not Treated*: 2								
Patient ID (Entry Date): 28(06/18/2003) 29(06/30/2003)								

* Excludes patients whose off treatment reason is 'Patient withdrawal/refusal before beginning protocol therapy' or 'Disease Progression before Active Treatment' or 'No treatment per protocol criteria'

Page: 2 of 2

Figure 54 – Sample Open Protocols with no Treatments Report

The Open Protocols with no Adverse Events Report

This report displays lead organizations that have protocols and patients accrued along with treatments but no adverse event reported. The information is grouped by the lead organization.

Running the Report

1. Click the checkbox to the left of **Open Protocols with no Adverse Events**.

   Parameters appear in the right frame as shown in Figure 55.

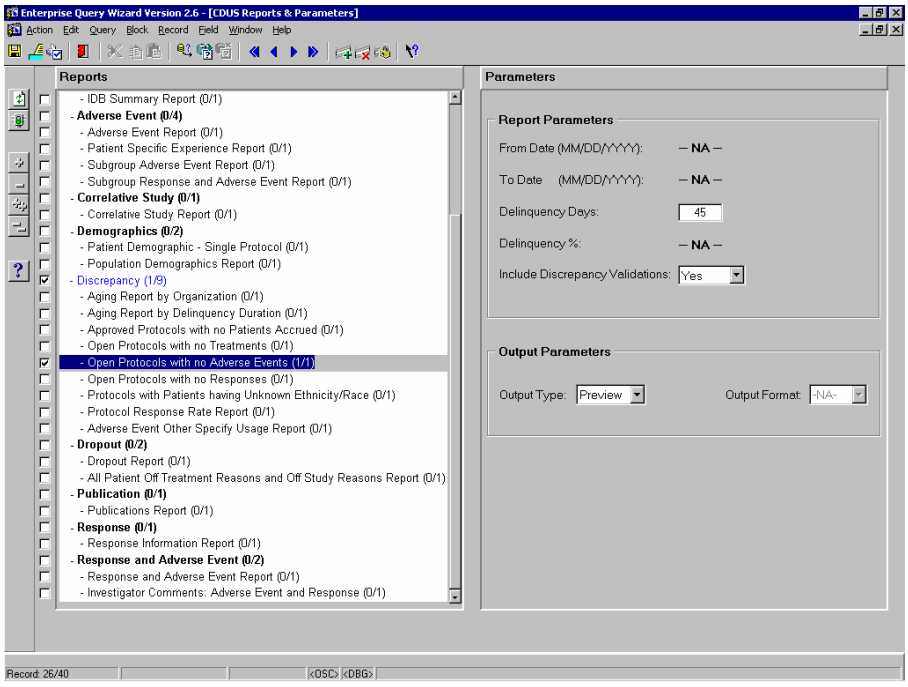

Figure 55 – Open Protocols with no Adverse Events Report Parameters

2. Enter the number of **Delinquency Days** up to 365. (The default is 45.)
3. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency Days (up to 365)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol.
- **No. of Patients Registered:** The total number of patients entered on the protocol.
- **No. of Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Validation for Discrepancy** The validated and documented discrepancy.
- **No. of Patients with AE Experienced 'No':** The number of patients registered on the protocol for whom no adverse events have been recorded.
- **No. of Patients with AE Experienced 'Too Early':** The number of patients registered on the protocol recorded as 'Too Early to Evaluate' for adverse events.
- **Patient IDs, Course ID, and Start Date where AE Experienced is 'No':** The SOURCE_PATIENT_ID, course number, and course start date on the protocol for patients having no adverse events recorded.
- **Patient IDs, Course ID, and Start Date where AE Experienced is 'Too Early to Evaluate':** The SOURCE_PATIENT_ID, course number, and course start date on the protocol for patients recorded as 'Too Early to Evaluate' for adverse events.

Business Rules

The report lists all open protocols and patients at that organization that:

1. Have treatments, and
2. No positive Response, and
3. Off treatment reason of the patient is 'Adverse Event/Side Effects/Complications,' and
4. No adverse event reported for a specific treatment course, and
5. Course start date of the treatment + X days should be less or equal to today's date where 'X' is a parameter defaulted to 45 and no greater than 365.

All protocols selected have the monitoring method 'Complete' for CDUS and CTMS protocols.

The report lists protocols with patients where adverse event experienced on a treatment is:

- No
- Too Early to Evaluate

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Open Protocols with no Adverse Events

Date: 07/12/2004

(45 days from Course Start Date - Validations for Discrepancy Included)

Lead Organization : MI014 - University of Michigan Medical Center

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	No. Patients Reg./Treated
198	Phase II Evaluation of Trastuzumab (Herceptin), Paclitaxel, Carboplatin, and Gemcitabine in the Treatment of Advanced Urothelial Cancer	Trastuzumab [Herceptin(R)]	Bladder cancer stage IV	Maha H. Hussain	II	CDUS - Complete	Active (03/23/2000) (08/13/2003)	28 / 28

Validation for Discrepancy: Reason for the Discrepancy

No. of Patients with AE Experienced of 'No': 2

Patient ID - Course No.(Start Date) where AE Experienced is 'No': 07-02 - 3(04/17/2003) 4(05/12/2003)
07-03 - 1(04/16/2003) 2(05/14/2003)

No. of Patients with AE Experienced of 'Too early': 1

Patient ID - Course No.(Start Date) where AE Experienced is 'Too early to evaluate': 03-02 - 1(04/24/2003)

Figure 56 – Sample Open Protocols with no Adverse Events Report

The Open Protocols with no Responses Report

This report displays all lead organizations that have protocols and patients accrued with treatments but no responses reported. The information displayed is grouped by the lead organization.

Running the Report

1. Click the checkbox to the left of **Open Protocols with no Responses**.

Parameters appear in the right frame as shown in Figure 57.

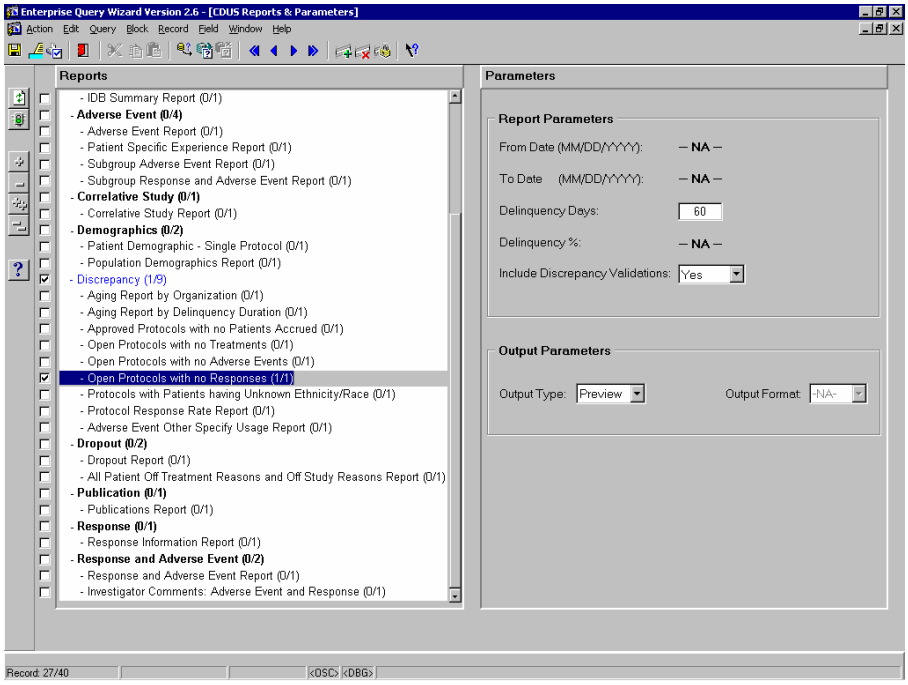

Figure 57 – Open Protocols with no Responses Report Parameters

2. Enter the number of **Delinquency Days** up to 365. (The default is 60.)
3. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency Days (up to 365)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **No. of Patients Registered:** The total number of patients entered on the protocol.
- **No. of Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Validation for Discrepancy** The validated and documented discrepancy.
- **Patient IDs and Entry Dates of patients with responses too early to evaluate:** The SOURCE_PATIENT_ID and entry date on the protocol for patients recorded as 'Too Early' for response.
- **Patient IDs and Entry Dates of patients with responses with no response:** The SOURCE_PATIENT_ID and entry date on the protocol for patients where no responses were recorded

Business Rules

The report lists all protocols and patients at that organization that:

1. Have treatments, and
2. No responses reported, and
3. Course start date of the treatment + X days should be less or equal to today's date where 'X' is a parameter defaulted to 60 and no greater than 365.

All protocols selected have the monitoring method ‘Complete’ for CDUS and CTMS protocols.

The report lists protocols with patients where no responses where reported since the first treatment and the response evaluation status is:

- No
- Too Early

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Open Protocols with no Responses

Date: 07/12/2004

(60 days from First Course Start Date - Validations for Discrepancy Included)

Lead Organization : MI014 - University of Michigan Medical Center

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	No. Patients Reg./Treated
198	Phase II Evaluation of Trastuzumab (Herceptin), Paclitaxel, Carboplatin, and Gemcitabine in the Treatment of Advanced Urothelial Cancer	Trastuzumab [Herceptin(R)]	Bladder cancer stage IV	Maha H. Hussain	II	CDUS - Complete	Active (03/23/2000) (08/13/2003)	28 / 28

Validation for Discrepancy: Reason for the Discrepancy

No. of Patients with Response Evaluation of 'No' : 2

Patient ID - Course No.(Start Date) where Response Evaluation is 'No' :
04-07 - 1(02/04/2003)
06-02 - 1(06/19/2001)

No. of Patients with Response Evaluation of 'Too early': 6

Patient ID - Course No.(Start Date) where Response Evaluation is 'Too early':
02-01 - 1(04/11/2003)
03-01 - 1(04/29/2002) 2(05/30/2002)
03-02 - 1(04/24/2003)
03-03 - 1(04/15/2003)
06-10 - 1(05/01/2003) 2(06/02/2003) 3(06/23/2003)
07-03 - 1(04/16/2003) 2(05/14/2003)

Page: 2 of 2

Figure 58 – Sample Open Protocols with no Responses Report

The Protocols with Patients having Unknown Ethnicity/Race Report

This report displays lead organizations that have protocols and accrued patients having unknown ethnicity or unknown race. The data is grouped by CTEP ID and sorted by protocol number.

Running the Report

1. Click the checkbox to the left of **Protocols with Patients having Unknown Ethnicity/Race**.

Parameters appear in the right frame as shown in Figure 59.

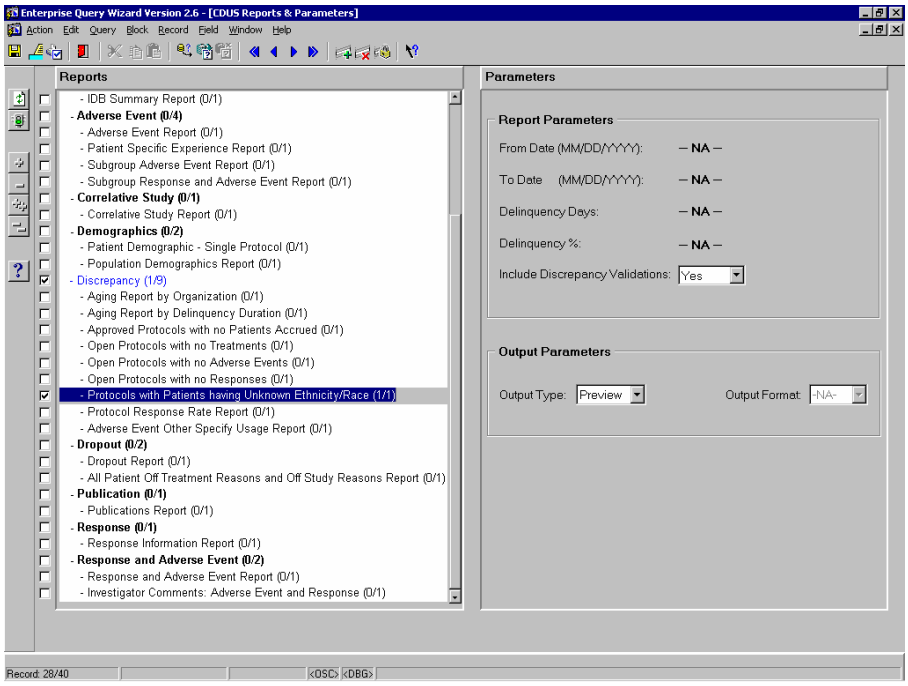

Figure 59 – Protocols with Patients having Unknown Ethnicity/Race Report Parameters

2. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.

3. Select **Preview** or **File** from the **Output Type** drop-down list.
4. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency % (up to 100)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol.
- **Total Accrual**: Number of patients accrued for the study.
- **Unknown Ethnicity Total**: The total number of patients accrued on the study with ethnicity defined as 'Unknown.'
- **Unknown Ethnicity (%)**: (Number of Patients accrued with ethnicity defined as 'Unknown' / Total number of patients accrued for the current trial) * 100
- **Unknown Race Total**: The total number of patients accrued on the study with race defined as 'Unknown.'
- **Unknown Race (%)**: (Number of Patients accrued with race defined as 'Unknown' / Total number of patients accrued for the current trial) * 100
- **Validation for Discrepancy** The validated and documented discrepancy.

Business Rules

The report lists all protocols that:

1. Have a status of 'Active,' ' Closed to Accrual,' 'Closed to Accrual & Treatment,' 'Temporarily Closed to Accrual,' 'Temporarily Closed to Accrual &Treatment,'
2. Have monitoring method of 'CDUS – Abbreviated,' 'CDUS – Complete,' 'CTMS (CDUS –Abbreviated),' 'CTMS (CDUS – Complete),'
3. Patient's ethnicity is 'Unknown' or race is 'Unknown,' and
4. The ratio of total 'Unknown Ethnicity/Race' to total accrual should be:

Total Accrual	Ratio
1–3	>= 50%
4–6	> 25%
7–9	> 20%
10+	>= 10%

(Low Delinquency is displayed in blue and High Delinquency is displayed in red.)

Based on the ratio and the number of accrual, 'Unknown Ethnicity' total and percent columns, and 'Unknown race' total and percent columns displays Low Delinquency in blue color and High Delinquency in red color.

The following discrepancy rules table for selecting unknown Ethnicity/Race is displayed at the end of the report:

No. of Patients	Low Delinquency	High Delinquency
1–3	>= 50%	N/A
4–6	> 25% – < 50%	>= 50%
7–9	> 20% – < 30%	>= 30%
10+	10%	> 10%

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Protocols with Patients having Unknown Ethnicity/Race
(Validations for Discrepancy Included)

Date: 07/12/2004

Lead Organization : MI014 - University of Michigan Medical Center

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	Total Accrual	Unknown			
									Ethnicity		Race	
									Total	%	Total	%
198	Phase II Evaluation of Trastuzumab (Herceptin), Paclitaxel, Carboplatin, and Gemcitabine in the Treatment of Advanced Urothelial Cancer	Trastuzumab [Herceptin(R)]	Bladder cancer stage IV	Maha H. Hussain	II	CDUS - Complete	Active (03/23/2000) (08/13/2003)	28	8	28.57	0	0.00
Validation for Discrepancy: Reason for the Discrepancy												

Delinquency rules for Unknown Ethnicity/Race

No. of Patients	Low Delinquency	High Delinquency
1-3	>= 50%	N/A
4-6	> 25% - < 50%	>= 50%
7-9	> 20% - < 30%	>= 30%
10+	10%	> 10%

Page: 2 of 2

Figure 60 – Sample Protocols with Patients having Unknown Ethnicity/Race Report

The Protocol Response Rate Report

The report displays all lead organizations that have protocols with more than 10 patients and where the response rate is greater than a threshold value. The main grouping is on the organization and sorted by protocol number in an ascending order.

Running the Report

1. Click the checkbox to the left of **Protocol Response Rate Report**.

Parameters appear in the right frame as shown in Figure 61.

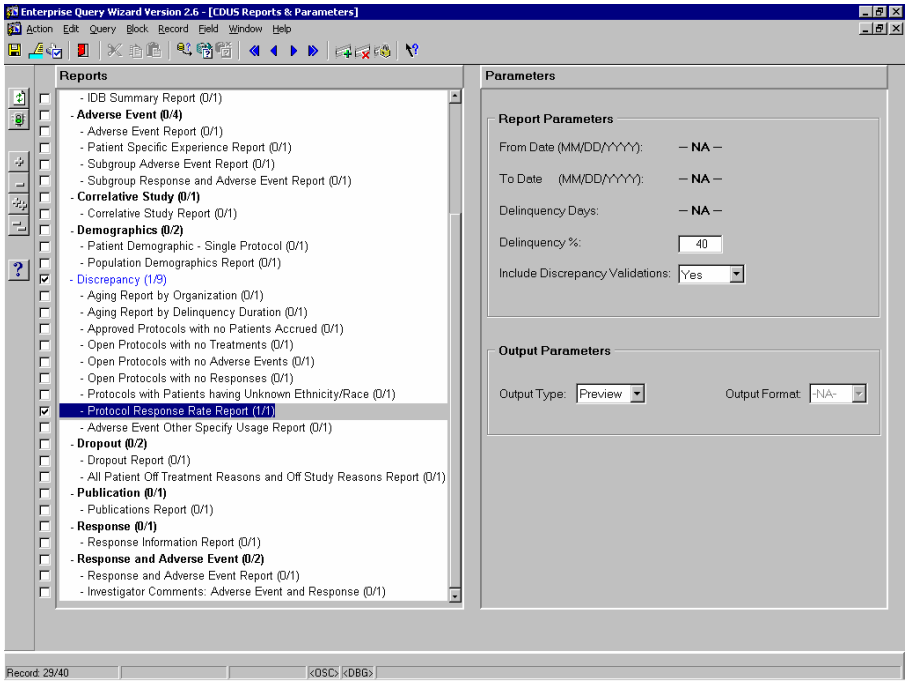

Figure 61 – Protocol Response Rate Report Parameters

2. Enter the value of **Delinquency %** up to 100. (The default is 40.)
3. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameter:

- Delinquency % (up to 100)

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Lead Agent:** The Agent Name of NSC identified as Lead Agent.
- **Lead Disease:** The preferred CTEP term for the lead disease being studied.
- **Principal Investigator:** The Principal Investigator for the protocol as entered in PATS.
- **Phase:** The protocol's phase (I, I/II, II, III, Other, Pilot) of clinical study.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Current Status Date:** The status date for the document.
- **Last Successful Submission Date** The last date that data was submitted successfully through CDUS for the protocol.
- **No. of Patients Registered:** The total number of patients entered on the protocol.
- **No. of Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Validation for Discrepancy** The validated and documented discrepancy.
- **Total patients evaluable for response:** Total number of patients on the study who are evaluable for response as submitted using CDUS.
- **Total patients where best response = 'Complete Response':** Counts of only those patients on the study who have the best response as 'Complete Response.'
- **Total patients where best response = 'Partial Response':** Counts of only those patients on the study who have the best response as 'Partial Response.'
- **RR (Response Rate):** The value displayed is based upon the formula RR = [(Number of patients with complete response + Number of patients with partial response) / Number of patients evaluated for response] *100

Business Rules

The report lists all protocols that have:

1. A status of 'Active,' 'Closed to Accrual,' 'Closed to Accrual & Treatment,' 'Temporarily Closed to Accrual,' 'Temporarily Closed to Accrual &Treatment,' and
2. A monitoring method of 'CDUS – Complete,' 'CTMS (CDUS – Complete),' and
3. Patients that are evaluable for response, and
4. A response rate greater than or equal to X percent, where 'X' is a parameter defaulted to 40.

Enhancements

This report is new with CDUS Report Writer version 4.0.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Response Rate Report

Date: 07/12/2004

Protocols where Response Rate is greater than or equal to 40 % - Validations for Discrepancy Included

Lead Organization : MI014 - University of Michigan Medical Center

Protocol No.	Title	Lead Agent	Lead Disease	Principal Investigator	Phase	Monitoring Method	Status (Status Date) (Last Subm. Date)	No. Patients Reg./Treated
198	Phase II Evaluation of Trastuzumab (Herceptin), Paclitaxel, Carboplatin, and Gemcitabine in the Treatment of Advanced Urothelial Cancer	Trastuzumab [Herceptin(R)]	Bladder cancer stage IV	Maha H. Hussain	II	CDUS - Complete	Active (03/23/2000) (08/13/2003)	28 / 28
Validation for Discrepancy: Reason for the Discrepancy								
Eval: 20 **CR:** 3 **PR:** 15 **RR(%):** 90.00								

Report displays protocols that have accrued more than or equal to 10 patients

Page: 2 of 2

Figure 62 – Sample Protocol Response Rate Report

The Adverse Event Other Specify Usage Report

The report lists all protocols having a minimum, user-specified number of adverse events where the use of 'other-specify' percentage is greater than or equal to a user-specified threshold value.

Running the Report

1. Click the checkbox to the left of **Adverse Event Other Specify Usage Report**.

Parameters appear in the right frame as shown in Figure 63.

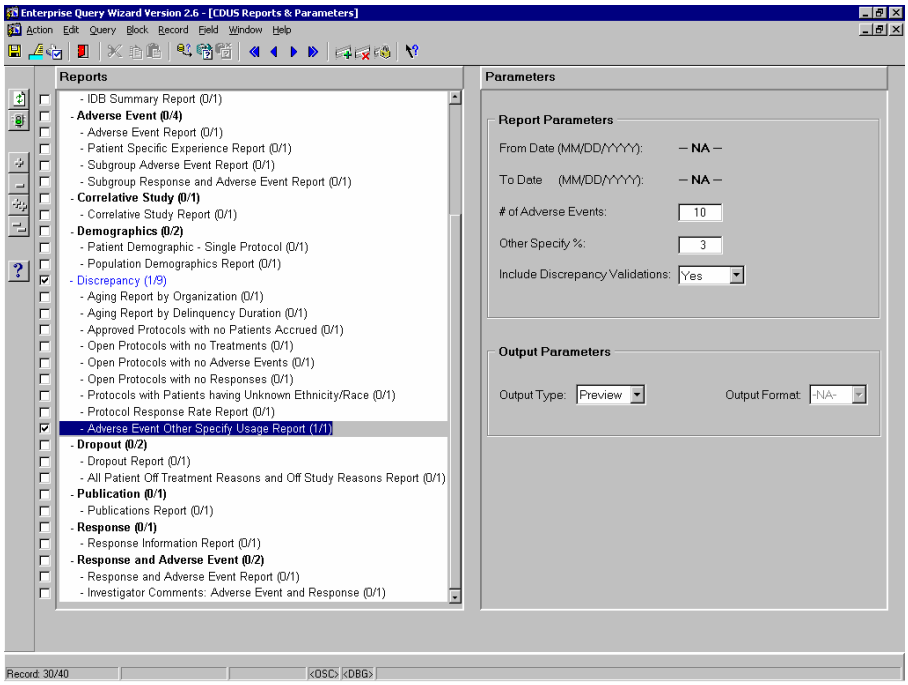

Figure 63 – Adverse Event Other Specify Usage Report Parameters

2. Enter the value of **# of Adverse Events**. This is the threshold value for the minimum number of adverse events reported on the study by CDUS.
3. Enter the value of **Other Specify %**. This is the minimum percentage of 'other specify' adverse events that protocols must have to be included on the report.
4. Select an **Include Discrepancy Validations** parameter from the drop-down list.

   Selecting "No" excludes protocols with validated discrepancies from the report. Selecting "Yes" includes all protocols with discrepancies along with any "Validation for Discrepancy" text.
5. Select **Preview** or **File** from the **Output Type** drop-down list.
6. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- # of Adverse Events
- Other Specify %

Field Definitions

The report displays the following protocol administrative information along with the protocol number:

- **Lead Organization:** The lead organization for the protocol.
- **Title:** The title of this document (i.e., LOI, Concept Review, or Protocol).
- **Status:** The current status of the protocol as entered in PATS.
- **Status Date:** The date for the current status as entered in PATS.
- **Last Submission Date** The last date that data was submitted successfully through CDUS for the protocol.
- **Total AE's:** The total number of adverse events on this protocol.
- **Total AE Other Specifies** The total number of adverse events with the use of 'other-specify'.
- **% AE Other Specify Usage:** The percentage of adverse events with the use of 'other-specify'.

Business Rules

1. The report lists all lead organizations that have protocols with more than or equal to X AE's (X being the first parameter displayed on the parameter screen) where the use of 'other specify' is greater than or equal to a threshold value.
2. The report displays the Validation for Discrepancy based on the parameter being parsed through EQW.

The main grouping of the report is on the organization and is sorted by % AE in ascending order.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Adverse Event Other Specify Usage Report

Date: 07/12/2004

Protocols where usage of Other Specify is greater than or equal to 3 % - Validations for Discrepancy Included

Lead Organization : OH007 - Ohio State University Hospital

Protocol No.	Title	Status	Status Date	Last Submission Date	Total AE's	Total AE Other Specifies	% AE Other Specify Usage
1254	Phase I Study of Thrice Weekly Hu1D10 in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma and Acute Lymphoblastic Leukemia	Closed to Accrual & Treatment	05/08/2003	10/31/2003	201	14	6.97
Validation for Discrepancy: Reason for the Discrepancy							

Report displays protocols that have more than or equal to 10 AE's

Page: 2 of 3

Figure 64 – Sample Adverse Event Other Specify Usage Report

The Dropout Reports

The Dropout Report

This report displays patients who have dropped out of the study.

Running the Report

1. Click the checkbox to the left of **Dropout Report**.

Parameters appear in the right frame as shown in Figure 65.

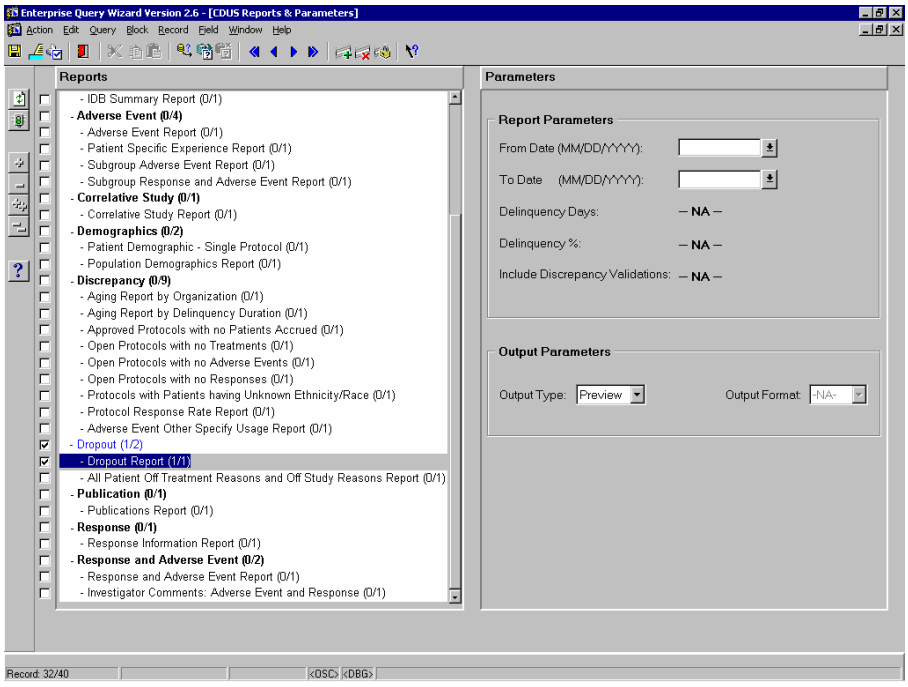

Figure 65 - Dropout Report Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.

5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

- **Protocol Number – Title:** The unique identifier for a document. – The title of the document
- **Status/ Date:** The current status/status date on the protocol as entered in PATS.
- **Activation Date:** The activation date for the protocol as entered in PATS. For a re-activated study, this date will reflect the initial activation date.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered in the current protocol as submitted using CDUS.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol as entered in PATS.
- **Patient ID:** The patient's SOURCE_PATIENT_ID as submitted using CDUS.
- **Treatment Assignment:** The patient's TRT_ASGNMT_CODE as submitted using CDUS.
- **Treatment Start Date:** The COURSE_START_DATE for the first treatment course for the patient, i.e., the minimum COURSE_START_DATE for the patient.
- **No. of Courses:** The total number of treatment courses for the patient.
- **Dropout Reason:** The OFF_TX_REASON for the patient. The reason the patient went off treatment or therapy.
- **Time to Last Treatment:** Length of time (in days) that this patient was on treatment or therapy.

Business Rules

The following business rules determine the report's output.

- **Treatment Assignment:** The treatment assignment the patient was on when he/she dropped out.

- **Dropout Reason:** The condition for dropout is defined as follows:
  1. The patient has an off treatment reason (excluding 'Treatment completed per protocol criteria' and 'No treatment per protocol criteria').
  2. The Patient records with exactly one treatment course and where the Off Treatment Reason is 'Disease progression, relapse during active treatment', and the best response for the patient is 'Complete Response', 'Partial Response', or 'Less than Partial Response', or 'Stable' are excluded from the report.
  3. The Patient records with two or more treatment courses and where the Off Treatment Reason is 'Disease progression, relapse during active treatment' are excluded from the report.
  4. The Patient records with the dropout reason set to 'Treatment Completed per Protocol Criteria' or 'No treatment per protocol criteria' are excluded from the report.

- **Treatment Start Date** The date that the patient started a course of treatment. This report identifies just the first Course Start Date.

- **Time to Last Treatment:** This calculation is based on the Last Treatment Date of the patient, if available, or else the Last Treatment Course Start Date. Wherever the calculation is based on the Last Treatment Date, an asterisk (*) is displayed. The meaning of the asterisk (*) is displayed in a footnote.

  If Patient: Last Treatment Date is available, Time to Last Treatment is calculated as the difference between Last_Treatment_Date and first treatment Course_Start_Date.

  If Patient: Last Treatment Date is not available, Time to Last Treatment is calculated as the difference between last treatment Course_Start_Date and first treatment Course_Start_Date.

  If 0, then a "–" is displayed.

- **Ordering:** Doc# (if more than one), then order by treatment start date.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Dropout Report

Date : 09/28/2004

98 - A Phase I Scientific Exploratory Study of Epothilone B Analog (BMS-247550; NSC 710428) in Patients with Solid Tumors and Gynecological Malignancies

Status/ Date: Closed to Accrual & Treatment 05/14/2003 **Activation Date:** 02/25/2000 **Cutoff Date:** 10/31/2003 **Patients Registered/Treated:** 57 / 54

Lead IND: 59699 **Monitoring Method:** CTMS (CDUS - Complete) **NSC:** 710428, Epothilone-B BMS 247550

Patient ID	Treatment Assignment	Treatment Start Date	No. of Courses	Dropout Reason	Time to Last Treatment (Days)
0006-M02	TAC2	04/25/2000	1	Disease progression, relapse during active treatment	-
004	TAC6	06/13/2000	1	Death on Study	-
0006-N06	TAC4	07/31/2000	1	Disease progression, relapse during active treatment	-
0006-N09	TAC4	09/26/2000	1	Disease progression, relapse during active treatment	-
0006-N011	TAC4	10/03/2000	1	Death on Study	-
0006-M21	TAC3.1	12/21/2001	4	Death on Study	97
0006-M25	TAC3.1	02/11/2002	4	Alternative therapy	93
0006-M26	TAC3.1	02/13/2002	8	Adverse Event/Side Effects/Complications	147
0006-M32	TAC3.1	03/26/2002	1	Death on Study	-
0006-M33	TAC3	03/27/2002	6	Patient withdrawal/refusal after beginning protocol therapy	132
0006-N38	TAC3.1	05/13/2002	1	Disease progression, relapse during active treatment	-
0006-M41	TAC3.1	06/28/2002	1	Other	-
0006-N50	TAC3.1	09/09/2002	5	Other	105
0006-N51	TAC3	09/17/2002	2	Adverse Event/Side Effects/Complications	20
0006-N55	TAC3.1	02/10/2003	1	Death on Study	-

* Time to Last Treatment is based on the Last Treatment Date of the patient instead of the Last Treatment Course Start Date if the Last Treatment Date is available.
** Patients meeting the following criteria are not displayed on this report:
- Off Treatment Reason is 'Treatment Completed Per protocol Criteria'
- Off Treatment Reason is 'No treatment per protocol criteria'
- Number of treatment courses is one and Off Treatment Reason is 'Disease progression, relapse during active treatment', and the best response for the patient is ' Complete Response', 'Partial Response', 'Less than Partial Response', or 'Stable'
- Number of treatment courses is two or more and Off Treatment Reason is 'Disease progression, relapse during active treatment'

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Figure 66 – Sample Dropout Report

The All Patient Off Treatment Reasons and Off Study Reasons Report

This report displays all patients who are no longer on a study or are no longer receiving treatment along with their Off Study Reasons and Off Treatment Reasons. There are no filters on either of these fields; all Off Treatment Reasons and Off Study Reasons are identified as reported.

Running the Report

1. Click the checkbox to the left of **All Patient Off Treatment Reasons and Off Study Reasons Report**.

Parameters appear in the right frame as shown in Figure 67.

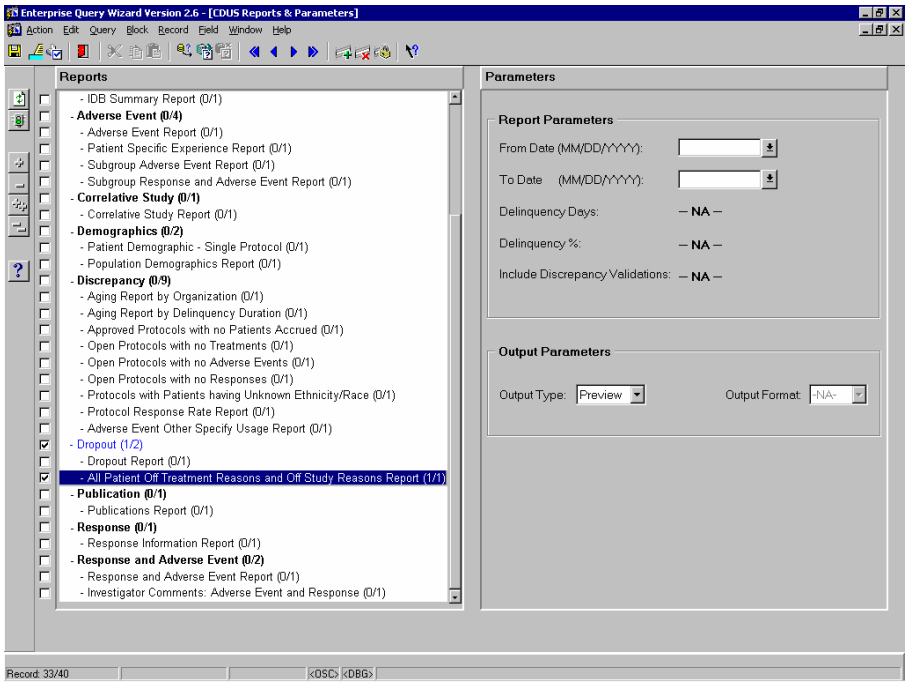


Figure 67 - All Patient Off Treatment Reasons and Off Study Reasons Report Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.
5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

- **Protocol Number – Title:** The unique identifier for a document. – The title of the document
- **Status/ Date:** The current status/status date on the protocol as entered in PATS.
- **Activation Date:** The activation date for the protocol as entered in PATS. For a re-activated study, this date will reflect the initial activation date.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered in the current protocol as submitted using CDUS.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol as entered in PATS.
- **Patient ID:** The patient's SOURCE_PATIENT_ID as submitted using CDUS.
- **Treatment Assignment:** The patient's TRT_ASGNMT_CODE as submitted using CDUS.
- **Treatment Start Date:** The COURSE_START_DATE for the first treatment course for the patient, i.e., the minimum COURSE_START_DATE for the patient.
- **No. of Courses:** The total number of treatment courses for the patient.
- **Off Treatment Reason:** The reason that the patient went off treatment or therapy.
- **Off Study Reason:** The OFF_STUDY_REASON for the patient. The reason the patient was removed from the study.
- **Time to Last Treatment:** Length of time (in days) that this patient was on treatment or therapy.

Business Rules

The following business rules determine the report's output.

- **Treatment Assignment:** The most recent TRT_ASGNMT_CODE for the patient is displayed, i.e., the treatment assignment associated with the treatment course with the maximum COURSE_START_DATE is displayed for the patient.

- **Treatment Start Date** The date that the patient started a course of treatment. This report identifies just the first Course Start Date.

- **Time to Last Treatment:** This calculation is based on the Last Treatment Date of the patient, if available, or else the Last Treatment Course Start Date. Wherever the calculation is based on the Last Treatment Date, an asterisk (*) is displayed. The meaning of the asterisk (*) is displayed in a footnote.

  If Patient: Last Treatment Date is available, Time to Last Treatment is calculated as the difference between Last_Treatment_Date and first treatment Course_Start_Date.

  If Patient: Last Treatment Date is not available, Time to Last Treatment is calculated as the difference between last treatment Course_Start_Date and first treatment Course_Start_Date.

  If 0, then a "–" is displayed.

- **Ordering:** Doc# (if more than one), then order by treatment start date.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

All Patient Off Treatment Reasons and Off Study Reasons Report

Date : 07/07/2004

E3198 - A Safety and Efficacy Study of Doxil and Taxotere +- Herceptin in Advanced Breast Cancer

Status/ Date: Active 01/04/2001 **Activation Date:** 01/04/2001 **Cutoff Date:** 06/30/2003 **Patients Registered/Treated:** 60 / 52

Lead IND: 6667 **Monitoring Method:** CDUS - Abbreviated **NSC:** 613795, GM-CSF (Sargramostim)
614629, G-CSF (AMGEN)
628503, DOCETAXEL (TAXOTERE)
712227, Liposomal Doxorubicin (Doxil)
688097, Trastuzumab [Herceptin(R)]
36225, Pyridoxine (Vitamin B6)

Patient ID	Treatment Assignment	Treatment Start Date	No. of Courses	Off Treatment Reason	Off Study Reason	Time to Last Treatment (Days)
31001	C	01/11/2001	5	Adverse Event/Side Effects/Complications	-	85
31004	C	01/25/2001	19	Disease progression, relapse during active treatment	-	420
31005	B	01/31/2001	3	Disease progression, relapse during active treatment	-	50
31003	B	02/01/2001	15	Treatment Completed Per protocol Criteria	-	301
31006	B	02/05/2001	1	Death on Study	-	-
31008	B	03/21/2001	8	Adverse Event/Side Effects/Complications	-	176
31012	B	05/30/2001	4	Adverse Event/Side Effects/Complications	-	69
31015	C	06/13/2001	27	Disease progression, relapse during active treatment	-	618
31013	B	06/14/2001	8	Other	-	153
31014	B	06/15/2001	8	Treatment Completed Per protocol Criteria	-	147
31017	C	06/28/2001	6	Disease progression, relapse during active treatment	-	106
31018	C	07/11/2001	5	Disease progression, relapse during active treatment	-	84
31021	C	07/24/2001	4	Disease progression, relapse during active treatment	-	64
31019	B	07/30/2001	6	Adverse Event/Side Effects/Complications	-	109
31023	C	08/13/2001	4	Disease progression, relapse during active treatment	-	72
31026	C	09/13/2001	4	Disease progression, relapse during active treatment	-	64

*Time to Last Treatment is based on the Last Treatment Date of the patient instead of the Last Treatment Course Start Date if the Last Treatment Date is available.
** Off Study Reason is only required for protocols activated on or after 01/01/2002.

Page 2 of 5

Figure 68 – Sample All Patient Off Treatment Reasons and Off Study Reasons Report

The Publications Report

This report displays the relationship between documents, publications, and authors.

Running the Report

1. Click the checkbox to the left of **Publications Report**.

Parameters appear in the right frame as shown in Figure 69.

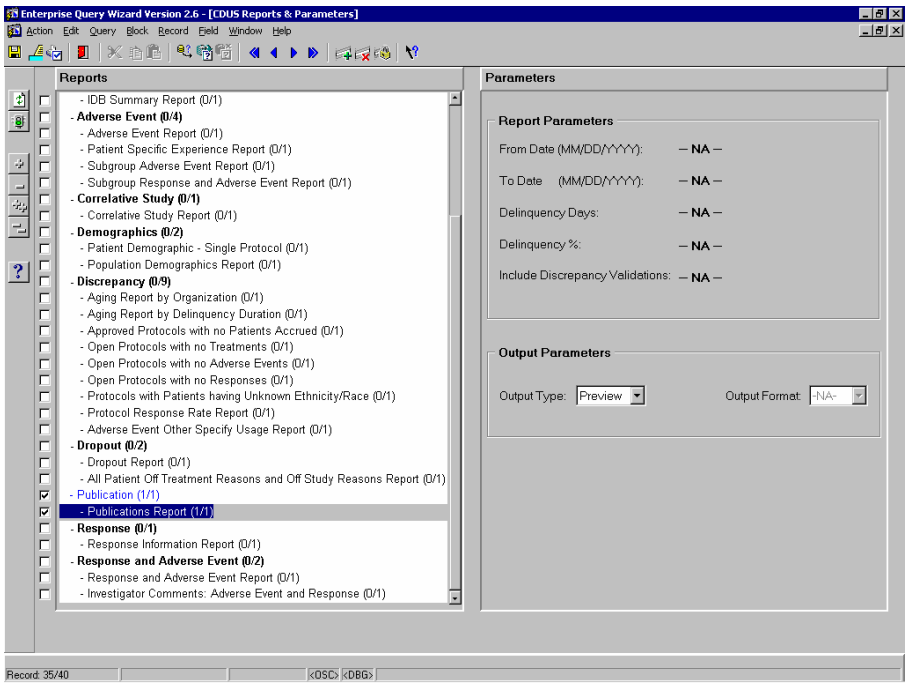


Figure 69 - Publications Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Phase:** The phase for the protocol.
- **Lead Organization:** The lead organization for the protocol + " / " + the principal investigator for the protocol as entered in PATS.
- **Current Status , Status Date:** The current status of the protocol + ", " + the current status date for the protocol as entered in PATS.
- **Lead NSC:** The NSC + "," + NAME for the lead NSC for the protocol as entered in PATS.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Publication Title*:** The title of this Publication. (e.g. "Effectiveness of Taxol plus Cisplatin"). There can be more than one publication (so as Publication Title) for a protocol.
- **Journal***: The name of the journal where the article or the paper was published (e.g., Journal of the American Medical Association).
- **Volume***: The volume number of the journal.
- **Year***: The year this article or abstract was published.
- **Pages*:** The first and last page numbers to indicate the length of the publication.
- **Medline_Uid***: The National Library of Medicine (NLM) unique 8 digit code supplied for the publication.
- **Authors***: For one publication there can be many authors which are separated by an ';'.

* Represents Publication data that is linked to the document via PDQ download, via CIBISCIT and via SMARTS. It does not represent the data submitted by the sites via CDUS data capture.

Business Rules

Business rules do not determine this report's output.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Publications Report

Date : 12/21/2006

1652 - A Phase II Study of Oxaliplatin in Relapsed and Refractory Non-Hodgkin's Lymphoma

Phase: II **Lead Organization/PI:** M.D. Anderson Cancer Center / Anas Younes **Current Status, Status Date:** Administratively Complete, 08/15/2005

Lead IND#: 57004 **Lead NSC#:** 266046, OXALIplatin (Eloxatin) **Cutoff Date:** 12/31/2005

1. Oki Y; McLaughlin P; Pro B; Hagemeister FB; Bleyer A; Loyer E; Younes A. Phase II study of oxaliplatin in patients with recurrent or refractory non-Hodgkin lymphoma.. Cancer. 104: 781-7, 2005. 15973667.

17 - A Randomized Phase II Trial of Weekly Docetaxel Plus Thalidomide Versus Weekly Docetaxel in Metastatic Androgen Independent Prostate Cancer

Phase: II **Lead Organization/PI:** National Cancer Institute Medicine Branch / William L. Dahut **Current Status, Status Date:** Complete, 07/14/2003

Lead IND#: 48832 **Lead NSC#:** 66847, Thalidomide (Thalomid) **Cutoff Date:** 01/08/2004

1. Dahut WL; Gulley JL; Arlen PM; Liu Y; Fedenko KM; Steinberg SM; Wright JJ; Parnes H; Chen CC; Jones E; Parker CE; Linehan WM; Figg WD. Randomized phase II trial of docetaxel plus thalidomide in androgen-independent prostate cancer.. J Clin Oncol. 22: 2532-9, 2004. 15226321.
2. Horne MK; Figg WD; Arlen P; Gulley J; Parker C; Lakhani N; Parnes H; Dahut WL. Increased frequency of venous thromboembolism with the combination of docetaxel and thalidomide in patients with metastatic androgen-independent prostate cancer.. Pharmacotherapy. 23: 315-8, 2003. 12627929.
3. Figg WD; Arlen P; Gulley J; Fernandez P; Noone M; Fedenko K; Hamilton M; Parker C; Kruger EA; Pluda J; Dahut WL. A randomized phase II trial of docetaxel (taxotere) plus thalidomide in androgen-independent prostate cancer.. Semin Oncol. 28: 62-6, 2001. 11685731.

1930 - A Phase I Trial and Pharmacokinetic Study of R115777 in Pediatric Patients with Refractory Leukemias

Phase: I **Lead Organization/PI:** National Cancer Institute Pediatric Oncology Branch / Brigitte C. Widemann **Current Status, Status Date:** Complete, 02/28/2005

Lead IND#: 58359 **Lead NSC#:** 702818, R115777 (tipifarnib, Zarnestra) **Cutoff Date:** 03/31/2005

--- No Records Found ---

Figure 70 – Sample Publications Report

The Response Report

This report provides information about the prior therapies that the patient has undergone. The report comprises two sections. The first section includes detailed response information for the patients on the protocol. The second section includes prior therapy information for each patient who had a response of Complete Response, Partial Response, or Less than Partial Response.

Running the Report

1. Click the checkbox to the left of **Response Information Report**.

Parameters appear in the right frame as shown in Figure 71.

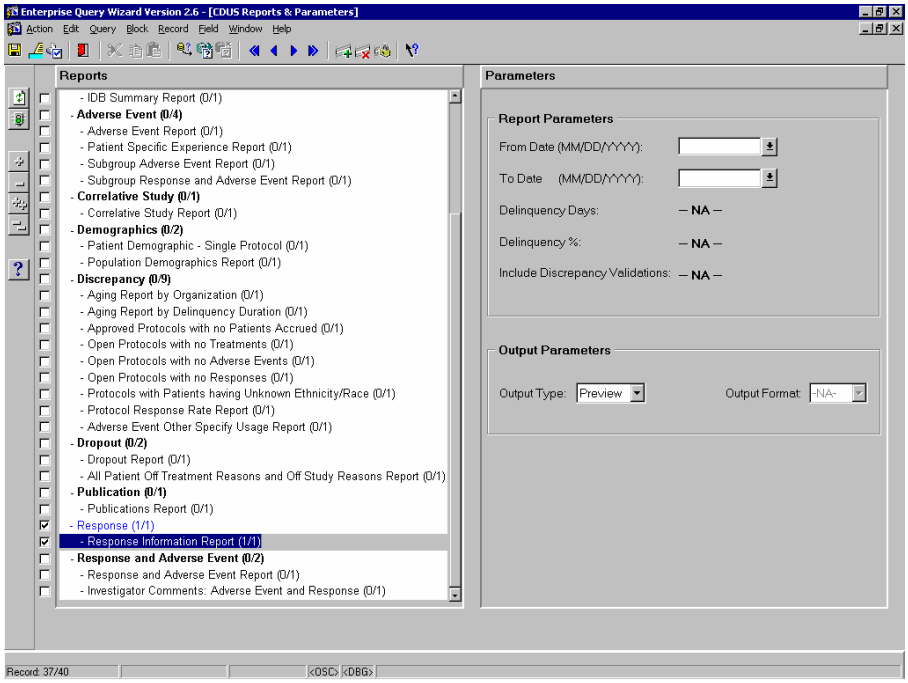


Figure 71 - Response Information Report Parameters

2. Select date in **From Date (MM/DD/YYYY)** field.
3. Select date in **To Date (MM/DD/YYYY)** field.
4. Select **Preview** or **File** from the **Output Type** drop-down list.

5. Click **Run**.

Changing the Report Output

The report output can be limited by the following parameters:

- Date of Entry Range (from and to dates)

Field Definitions

- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **NSC#:** The NSC + “, “ + NAME for all the NSCs for the protocol as entered in PATS.
- **Cutoff Date** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Activation Date** The activation date for the protocol as entered in PATS.
- **Patient ID:** The patient’s SOURCE_PATIENT_ID as submitted using CDUS.
- **Disease:** The CTEP_NAME for the patient’s disease as submitted using CDUS.
- **Starting Treatment Assignment** The patients’ starting TRT_ASGNMT_CODE.
- **Current Treatment Assignment:** The patient’s current TRT_ASGNMT_CODE.
- **No. of Courses:** The total number of treatment courses for the patient.
- **Time to Last Treatment:** Length of time (in days) that this patient was on treatment or therapy.
- **Time On Study (days):** See Business Rules and Enhancements.
- **Time to Progression (days):** The difference of the OBSERVED_DATE where the CATEGORY is “Progression” and the first treatment COURSE_START_DATE for the patient. /*If the value equals 0 then a “-“ is displayed.*/
- **Best Response Category:** The patient’s BEST_RESPONSE as submitted using CDUS.
- **Best Response Duration (days):** See Enhancements.
- **Treatment Assign-ment When Best** The patient’s TRT_ASGNMT_CODE at time of best

Response Occurred: response.

Business Rules

The following business rules determine the report's output.

- **Patient ID:** Only patients who have a treatment course are displayed.

- **Current Treatment Assignment:** The most recent TRT_ASGNMT_CODE for the patient is displayed. This is the treatment course with the maximum COURSE_START_DATE displayed for the patient.

- **Time to Last Treatment:** This calculation is based on the Last Treatment Date of the patient, if available, or else the Last Treatment Course Start Date. Wherever the calculation is based on the Last Treatment Date, an asterisk (*) is displayed. The meaning of the asterisk (*) is displayed in a footnote.

  If Patient: Last Treatment Date is available, Time to Last Treatment is calculated as the difference between Last_Treatment_Date and first treatment Course_Start_Date.

  If Patient: Last Treatment Date is not available, Time to Last Treatment is calculated as the difference between last treatment Course_Start_Date and first treatment Course_Start_Date.

  If 0, then a "–" is displayed.

- **Time On Study:** Time on study is calculated based on different scenarios:

  1) For protocols approved on or after 01/01/2002:

  If the patient is on study (i.e. the OFF_STUDY_DATE is NULL or 'No') then find the difference between latest Cutoff Date and minimum Course Start Date (Cutoff Date –Minimum Course Start Date). Also '+' is appended to indicate that the patient is still on study.

  2) For all protocols:

  If the patient is off study (i.e. the OFF_STUDY_FLAG is 'Yes') then find the difference between the Off Study Date and minimum Course Start Date (Off Study Date – Minimum Course Start Date).

  3) For protocols approved before 01/01/2002:

  Here the Off Study Date will not be available always. In such a case this date cannot be calculated and

"[1]" is displayed. The meaning of "[1]" is explained at the footer of the report.

- **Time to Progression:** If there is no observed date with a category of progression, then a "-" is displayed otherwise the calculated value is displayed i.e., a 0 is displayed if value calculated is zero.

- **Best Response:** The best response is the response which has the highest order in the response sequence:

  Complete Response>Partial Responses>Less than Partial Response>Stable>Progression>Not assessed adequately > Other.

  If no response exists for the patient and if RESP_EVAL_STATUS for that patient is 'No' then 'Inevaluable' is displayed.

  If RESP_EVAL_STATUS for that patient is 'Too Early' then 'Too Early' is displayed.

  If RESP_EVAL_STATUS for that patient is 'Not Applicable' then 'Not Applicable' is displayed else if RESP_EVAL_STATUS for that patient is 'Yes' then 'Evaluable for response is Yes, however no response has been reported' is displayed.

  Only therapies with a best response of Complete Response, Partial Response, or Less than Partial Response are listed.

- **Prior Therapy:** Prior Therapy is the CTEP_NAME for the prior therapies undergone by the patient and its count is displayed. Only therapies for patients with a best response of Complete Response, Partial Response, or Less than Partial Response are listed.

- **TA1, TA2:** The report displays on the last page a description of all the treatment assignments displayed on the report. The treatment assignment and its description are fetched from the TRT_ASGMNT_CODE and DESCRIPTION columns in the TRT_ASSIGNMENTS table.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- A new column has been added, "Duration of Best Response."
  - Duration of Best Response will be determined calculated for any individual who is evaluable for response and who has a 'positive' response (positive response = stable, partial or complete).

- The time (# of days) will be calculated based on the date of the BEST response (stable<partial<complete).
- If a patient progresses (i.e. response is progression) after having a positive response the *Duration of response = Date of progression - Date of Best response*.
- If a patient is off study for any reason after having a response the *Duration of response = Date off study - Date of best response*.
- The answer will be followed by an asterisk (*) to indicate that the patient was removed from study while they were still responsive to therapy.
- If a patient has had a positive response and they have NOT progressed or been removed from study *the Duration of response = Cut off date - Date of best response*.
- The answer will be followed by plus sign (+) to indicate that the response is still ongoing.

- The report displays those patients who have been treated. A double asterisk (**) indicates those patients who are ineligible but have responses.
- If Off_Study_Date does not exist for a patient on a protocol approved prior to 01/01/2002, "[1]" is inserted into the Time on Study field and "[2]" is inserted into the Best Response Duration field.
- An appendix has been added to the report to show the treatment assignment code that is being used along with a description.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Clinical Trial Summary: Response Information Report

Date: 09/28/2004

N997B - A Phase II Study of CCI-779 in Patients with Recurrent Glioblastoma Multiforme

Lead IND# :61010 **NSC# :** 683864, CCI-779 Rapamycin Analog **Cutoff Date :** 09/30/2003

Activation Date: 05/11/2001

Patient ID	Disease	Starting Treatment Assignment	Current Treatment Assignment	No. of Courses	Time to Last Treatment (days)	Time on Study (days)	Time to Progression (days)	Best Response		Trt. Asgmt When Best Response Occurred
								Category	Duration (days)	
9032380	Glioblastoma multiforme	TAC1	TAC1	1	7	[1]	-	Other		TAC1
9034518	Glioblastoma multiforme	TAC1	TAC1	2	38	[1]	-	Other		TAC1
9034648	Glioblastoma multiforme	TAC1	TAC1	2	44	[1]	-	Other		TAC1
9032684	Glioblastoma multiforme	TAC1	TAC1	7	188	[1]	188	Partial Response	133	TAC1
5464588	Glioblastoma multiforme	TAC1	TAC1	2	47	[1]	47	Partial Response	19	TAC1
6082937	Glioblastoma multiforme	TAC1	TAC1	3	55	[1]	-	Partial Response	[2]	TAC1
6083870	Glioblastoma multiforme	TAC1	TAC1	4	83	[1]	-	Partial Response	[2]	TAC1
9034428	Glioblastoma multiforme	TAC1	TAC1	2	58	[1]	-	Partial Response	[2]	TAC1
9032907	Glioblastoma multiforme	TAC1	TAC1	2	53	[1]	57	Progression		TAC1
9032984	Glioblastoma multiforme	TAC1	TAC1	2	56	[1]	56	Progression		TAC1
9033405	Glioblastoma multiforme	TAC1	TAC1	2	41	[1]	41	Progression		TAC1
9033551	Glioblastoma multiforme	TAC1	TAC1	1	32	[1]	29	Progression		TAC1
6012310	Glioblastoma multiforme	TAC1	TAC1	1	27	[1]	27	Progression		TAC1
6033818	Glioblastoma multiforme	TAC1	TAC1	2	93	[1]	93	Progression		TAC1
6038327	Glioblastoma multiforme	TAC1	TAC1	1	-	[1]	29	Progression		TAC1
9030050	Glioblastoma multiforme	TAC1	TAC1	2	57	[1]	57	Progression		TAC1
9030064	Glioblastoma multiforme	TAC1	TAC1	1	7	[1]	7	Progression		TAC1
9032399	Glioblastoma multiforme	TAC1	TAC1	1	28	[1]	28	Progression		TAC1
9032431	Glioblastoma multiforme	TAC1	TAC1	2	43	[1]	43	Progression		TAC1
9032476	Glioblastoma multiforme	TAC1	TAC1	2	53	[1]	53	Progression		TAC1
9033252	Glioblastoma multiforme	TAC1	TAC1	5	117	[1]	-	Stable	[2]	TAC1
9033342	Glioblastoma multiforme	TAC1	TAC1	2	66	[1]	66	Stable	28	TAC1
9033372	Glioblastoma multiforme	TAC1	TAC1	10	260	[1]	-	Stable	[2]	TAC1

* - Patient is off study.
** - Patient is ineligible.
\+ - Patient is still on study.
[1] - Time on study may not be calculated for off study patients with protocols activated prior to 01/01/2002.
[2] - Best response duration may not be calculated for patients with protocols activated prior to 01/01/2002.

Figure 72 – Sample Response Information Report (page 1 of 2)

Clinical Trial Summary: Response Information Report

Date: 09/28/2004

Patient ID	Disease	Starting Treatment Assignment	Current Treatment Assignment	No. of Courses	Time to Last Treatment (days)	Time on Study (days)	Time to Progression (days)	Best Response		Trt. Asgmt When Best Response Occurred
								Category	Duration (days)	
9033416	Glioblastoma multiforme	TAC1	TAC1	1	17	[1]	-	Stable	[2]	TAC1
9033607	Glioblastoma multiforme	TAC1	TAC1	8	221	[1]	175	Stable	83	TAC1
9033796	Glioblastoma multiforme	TAC1	TAC1	6	167	[1]	167	Stable	111	TAC1
3389874	Glioblastoma multiforme	TAC1	TAC1	2	45	[1]	45	Stable	18	TAC1
4682292	Glioblastoma multiforme	TAC1	TAC1	4	126	[1]	-	Stable	[2]	TAC1
5320468	Glioblastoma multiforme	TAC1	TAC1	2	57	[1]	57	Stable	29	TAC1
6010962	Glioblastoma multiforme	TAC1	TAC1	5	147	[1]	147	Stable	119	TAC1
6115881	Glioblastoma multiforme	TAC1	TAC1	1	43	[1]	-	Stable	[2]	TAC1
9029437	Glioblastoma multiforme	TAC1	TAC1	5	135	[1]	-	Stable	[2]	TAC1
9030034	Glioblastoma multiforme	TAC1	TAC1	2	43	[1]	-	Stable	[2]	TAC1
9031101	Glioblastoma multiforme	TAC1	TAC1	2	49	[1]	42	Stable	16	TAC1
9031202	Glioblastoma multiforme	TAC1	TAC1	4	106	[1]	-	Stable	[2]	TAC1
9034332	Glioblastoma multiforme	TAC1	TAC1	5	112	[1]	-	Stable	[2]	TAC1
9034338	Glioblastoma multiforme	TAC1	TAC1	2	28	[1]	-	Stable	[2]	TAC1
9034556	Glioblastoma multiforme	TAC1	TAC1	3	54	[1]	-	Stable	[2]	TAC1
9028789	Glioblastoma multiforme	TAC1	TAC1	1	32	[1]	-	Too Early		-
9029733	Glioblastoma multiforme	TAC1	TAC1	1	21	[1]	-	Too Early		-

- **Median:** 53

* - Patient is off study.
** - Patient is ineligible.
\+ - Patient is still on study.
[1] - Time on study may not be calculated for off study patients with protocols activated prior to 01/01/2002.
[2] - Best response duration may not be calculated for patients with protocols activated prior to 01/01/2002.

Figure 73 – Sample Response Information Report (page 2 of 2)

Response and Adverse Event Reports

The Response and Adverse Event Report

The Response and Adverse Event Report lists all adverse events by treatment assignments for course 1 and courses 2+. It also reports escalation and de-escalation from one treatment assignment (TA) to another and presents high level response and adverse event information.

Running the Report

1. Click the checkbox to the left of **Response and Adverse Event Report**.

Parameters appear in the right frame as shown in Figure 74.

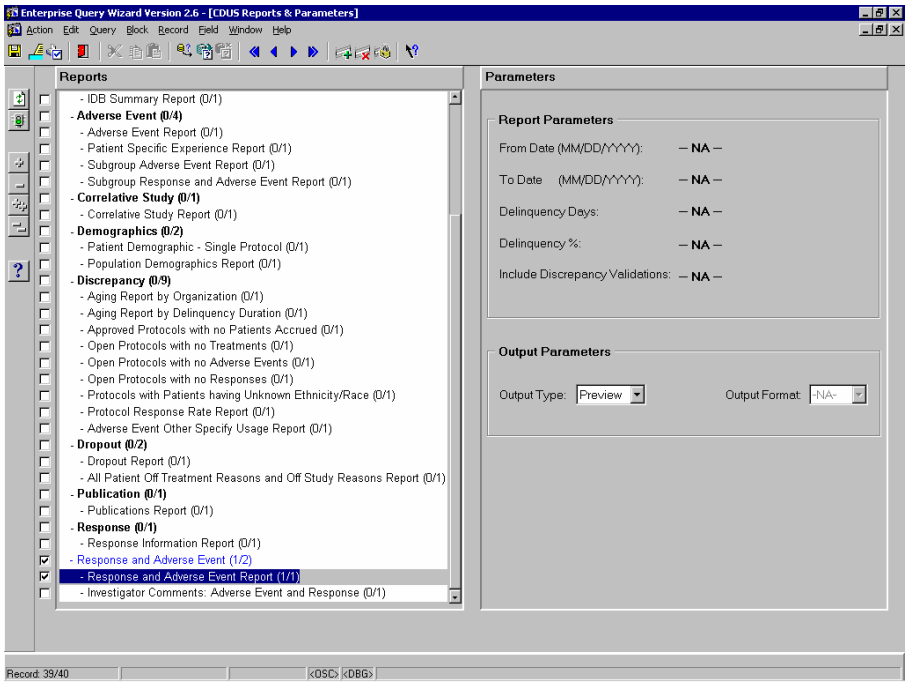


Figure 74 – Response and Adverse Event Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Lead Organization:** The active lead organization for the protocol + "/" + the principal investigator for the protocol as entered in PATS.
- **Current Status:** The current status of the protocol as entered in PATS.
- **Cutoff Date:** The cutoff date for the data displayed for the protocol as submitted using CDUS.
- **Patients Registered:** The total number of patients entered on the protocol as submitted using CDUS.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Patients on Study:** The total number of patients on this study.
- **Activation Date:** The activation date for the protocol as entered in PATS.
- **Monitoring Method:** The monitoring method for the protocol as entered in PATS.
- **Planned Accrual:** The planned range of patient accrual. The min accrual + "–" + the max accrual is displayed as entered in PATS.
- **Prior Therapy Eligibility Criteria:** The prior therapy eligibility criteria for the protocol as entered in PATS.
- **Lead Disease:** The lead disease(s) being studied on the protocol as entered in PATS.
- **Funding Information:** The grant(s) on the protocol as entered in FIATS.
- **Dose Limiting Adverse Events** Dose limiting toxicities for the protocol as reported using CDUS. If no record is found then the text "Not Reported" is displayed.
- **Recommended Phase II dose** Recommended phase II dose for the protocol as reported using CDUS. If no

record is found then the text "Not Reported" is displayed.

- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **NSC:** The NSC + "," + NAME for all the NSCs for the protocol as entered in PATS.
- **Total # Courses for all Patients:** The total number of courses for all patients on the protocol.
- **Median # Courses/Patient:** The median number of courses across all patients.
- **Treatment Assignments:** TRT_ASGNMT_CODE + "–" + DESCRIPTION.
- **Eval . for Response:** Total number of patients who are evaluable for response on a protocol as submitted using CDUS.
- **CR (Complete Response):** Total number of patients having complete response under that treatment assignment code.
- **PR (Partial Response):** Total number of patients having partial response under that treatment assignment code.
- **RR (Response Ratio):** The value displayed is based upon the formula RR = [(CR + PR) / Number of patients evaluated for response] *100 for a protocol.
- **Adverse Event count for a specified toxicity and grade**: The number printed at the intersection of the toxicity and grade represents the count of adverse events reported using CDUS for that toxicity and grade independent of the treatment course.

Business Rules

The following business rules determine the report's output.

- **Prior Therapy Eligibility Criteria:** If no record is found, then the text "No prior therapy eligibility criteria entered" is displayed.
- **Eval . for Response:** Only those patients who have the RESP_EVAL_STATUS as 'Yes' are counted. The patient is counted next to the treatment assignment to which he/she was originally assigned (i.e., the treatment assignment for

their first course).

- **Treatment Assignments:** The treatment assignments are displayed in ascending order by DOSE_LEVEL_ORDER.

- **CR (Complete Response):** CR (Complete Response) are counts of only those patients who have the Best Response as 'Complete Response'. The CR response will be attributed to the treatment only if:
  - It is only the treatment taken by the patient.
  - The response observed date is between the 3 days after including the treatment start date and 3 days after the next treatment started. For example, Patient PAT1 started on TAC0 on 12/01/2001, TAC1 on 01/01/2002 and was moved to TAC2 on 03/01/2002. A PR was observed on 03/02/2002 and CR was observed 03/5/2003. The PR will be attributed to the TAC1, CR will be attributed to TAC2. No responses will be attributed to TAC0.
  - The response observed 3 days after the last treatment will be attributed to the last treatment.
  - The response observed date lies between a two treatment assignment then the response is attributed to the previous treatment assignment.

- **PR (Partial Response):** PR (Partial Response) are counts of only those patients who have the Best Response as 'Partial Response'. The PR response will be attributed to the treatment only if:
  - It is only the treatment taken by the patient.
  - The response observed date is between the 3 days after including the treatment start date and 3 days after the next treatment started. For example, Patient PAT1 started on TAC0 on 12/01/2001, TAC1 on 01/01/2002 and was moved to TAC2 on 03/01/2002. A PR was observed on 03/02/2002 and CR was observed 03/5/2003. The PR will be attributed to the TAC1, CR will be attributed to TAC2. No responses will be attributed to TAC0.
  - The response observed 3 days after the last treatment will be attributed to the last treatment.
  - The response observed date lies between a two treatment assignment then the

response is attributed to the previous treatment assignment.

- **Adverse Event count for a specified toxicity and grade**: For a given patient for a given toxicity type, only the worst grade of that toxicity is counted.

  For example, if the patient had a Grade 2 Hematology toxicity in his 1st, 2nd and 3rd course, and a Grade 3 Hematology toxicity in his 4th course, then it would be counted once under Grade 3 Hematology.

  Adverse events of Grade 1, 2, and 3 with an attribution of "unrelated" or "unlikely" will not be included in the report.

Enhancements

CDUS Report Writer version 3.0 and future releases include the following enhancements for this report:

- Add status date of the protocol.
- If the Adverse Event type is other, the AE_Other_Specify is displayed.
- The phase of the protocol is displayed.
- Below the treatment assignment, the following is displayed:
  - **# experiencing AE:** The number of patients in the current treatment assignment that have AE experienced = 'Yes.'
  - **# started in:** The number of patients who had the course with the minimum COURSE_START_DATE lying in the current treatment assignment.
  - **# escalated to:** The number of patients escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in that treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER less than the current treatment assignment's DOSE_LEVEL_ORDER.
  - **# de-escalated to:** The number of patients de-escalated from a treatment assignment to another if the maximum COURSE_START_DATE for that patient lies in the current treatment assignment and the minimum COURSE_START_DATE lies in a treatment assignment that has a DOSE_LEVEL_ORDER higher than the current treatment assignment's

DOSE_LEVEL_ORDER.

- **# treated:** The number of patients lying in the current treatment assignment.
- **# dose change:** The number of patients lying in the current treatment assignment and had a dose change flag of either 'Yes, planned' or 'Yes, unplanned.'

- If there is no response and there is treatment then display the treatment assignment and show the Eval. (Number of patients evaluated) as zero.

With CDUS Report Writer version 4.0 and future releases, the report displays the CTCAE version at the top of the report along with the Protocol Number and Title for a study. The Adverse Event information is displayed as a concatenation of the Adverse Event and Select AE.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.

Clinical Trial Summary : Response and Adverse Event Report

Date: 02/16/2005

T99-0010 - A Phase II Study of Oxaliplatin in Combination with Fluorouracil and Leucovorin and Carcinoma of the Esophagus and Gastric Cardia

Lead Organization/PI: University of Chicago / Ann M. Mauer

Current Status: Administratively Complete **Status Date:** 02/21/2003 **Cutoff Date:** 12/31/2002 **Patients Registered / Treated/ On Study:** 35 / 35 / 0

Activation Date: 12/07/1999 **Phase:** II **CTCAE Version:** 2.0 **Monitoring Method:** CDUS - Complete **Planned Accrual:** 12 - 37

Prior Therapy: N/A **Lead Disease:** Esophageal cancer, NOS **Funding Information:** N01 CM 17102

Dose Limiting Adverse Events : Not Reported **Recommended Phase II Dose:** Not Reported **Response Information:** **Eval:** 34 **RR(%) :** 41

Lead IND# : 57004 **NSC:** 19893 ,5-FLUOROURACIL
3590 ,CALCIUM LEUCOVORIN
266046 ,OXALIPLATIN

Total # of Courses (for all patients): 323 **Median # of Courses (per patient):** 7 **Range # of Courses (per patient):** 1-27

Treatment Assignment	Response CR	Response PR		Adverse Events Reported (All Courses)** Grade :	1	2	3	4	5
TA110015 - Oxaliplatin 85 mg/m2 IV over 2 hr on day 1 q2w. Leucovorin 500 mg/m2 IV over 2 hr on day 1 after the completion of Oxaliplatin infusion q2w. Fluorouracil 400 mg/m2 IV bolus on days 1 & 2 after the completion of Leucovorin infusion q2w. Fluorouracil 600 mg/m2 IV over 22 hr on days 1 & 2 starting STAT after Fluorouracil IV bolus q2w.	1	13	ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)	1	1		1	
				Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	2				
			BLOOD/BONE MARROW	Hemoglobin	17	9	3		
				Hemolysis (e.g., immune hemolytic anemia, drug related hemolysis, other)	1				
				Leukocytes (total WBC)	6	14	7	1	
				Lymphopenia	2	3	5		
				Neutrophils/granulocytes (ANC/AGC)	2	3	12	11	
				Platelets	14	2	2	1	
			CARDIOVASCULAR (ARRHYTHMIA)	Sinus tachycardia	1				
			CARDIOVASCULAR (GENERAL)	Cardiac-ischemia/infarction			1		
				Edema	2				
				Hypertension	1				

 # experiencing AE: 35
 # started in: 35
 # escalated to: 0
 # de-escalated to: 0
 # treated: 35
 # dose change: 0

** This report includes grade 3, 4 and 5 events regardless of attribution and grades 1 and 2 events with a possible to definite attribution.
*** RR(%) exceeds 100% for the protocols with patients having Evaluation Status = 'No'. This is an exemption of the rule.

Page 2 of 6

Figure 75 – Sample Response and Adverse Event Report

The Investigator Comments: Adverse Event and Response Report

The Investigator Comments: Adverse Event and Response report lists comments concerning toxicities and responses.

Running the Report

1. Click the checkbox to the left of Investigator Comments: Adverse Event and Response Report.

Parameters appear in the right frame as shown in Figure 76.

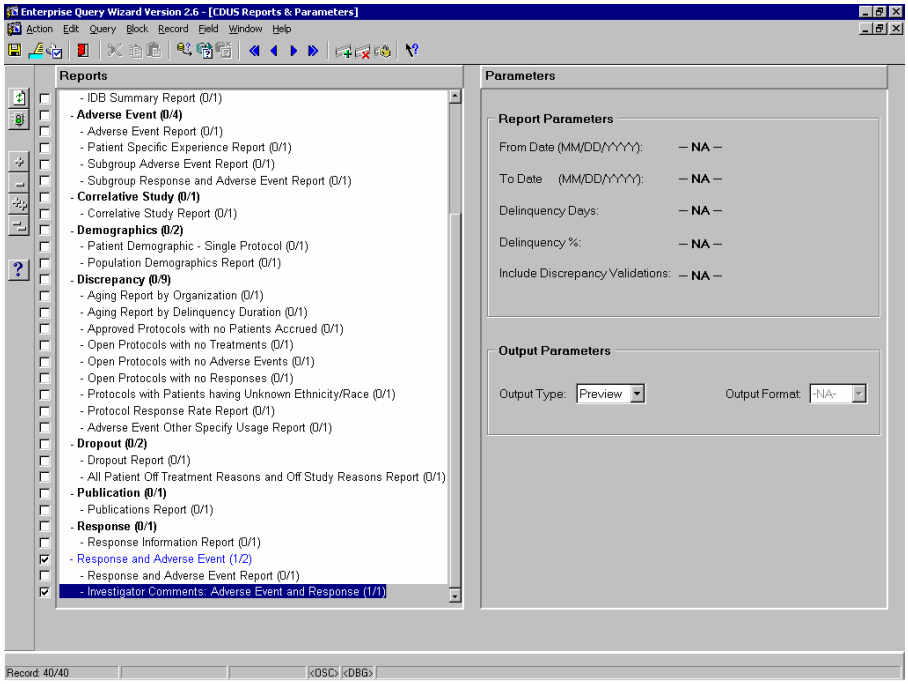


Figure 76 - Investigator Comments: Adverse Event and Response Report Parameters

2. Select **Preview** or **File** from the **Output Type** drop-down list.
3. Click **Run**.

Changing the Report Output

This report does not have parameters that change its output.

Field Definitions

- **Phase:** The phase for the protocol.
- **Lead Organization:** The lead organization for the protocol + " / " + the principal investigator for the

protocol as entered in PATS.

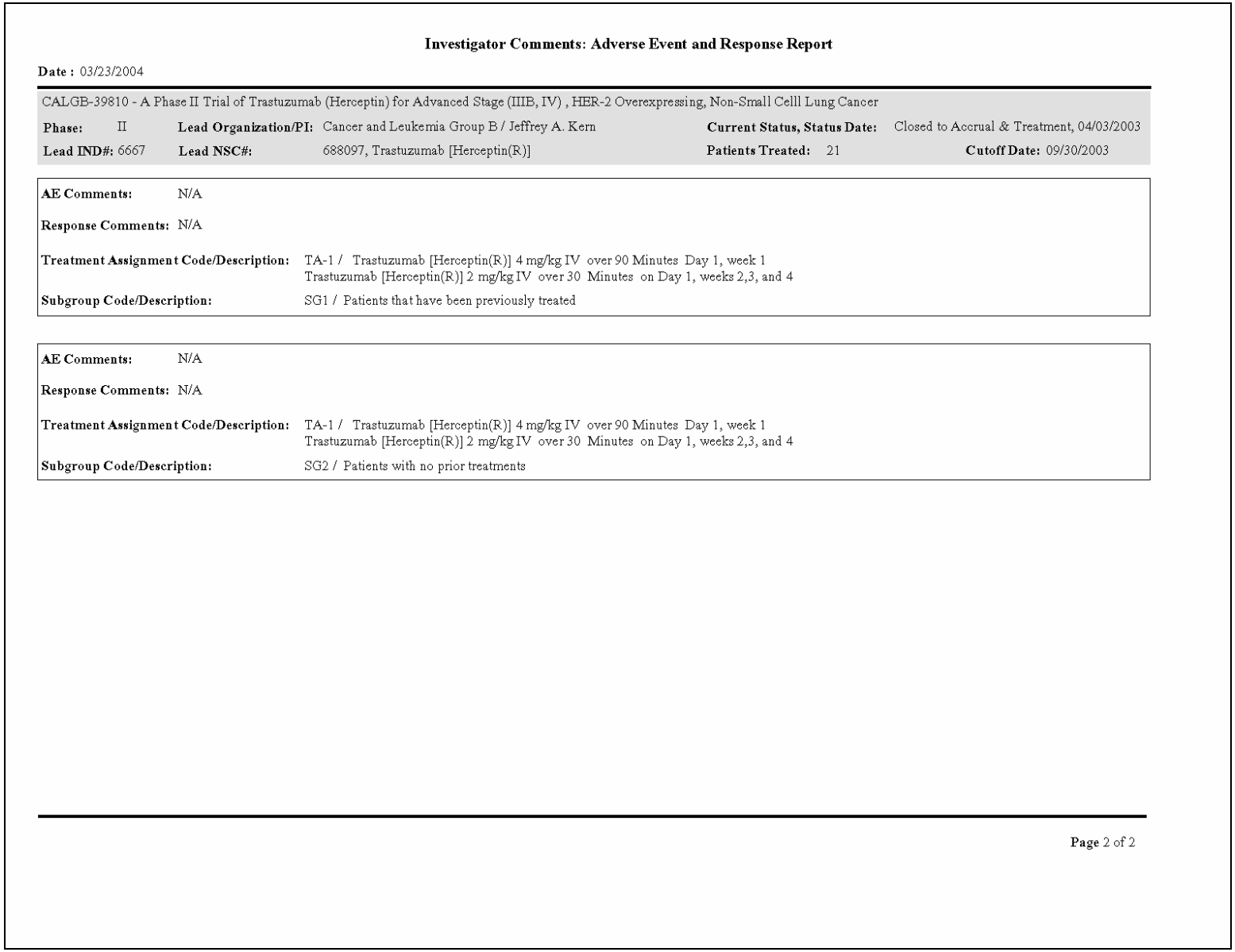
- **Current Status, Status Date:** The current status of the protocol + " , " + the current status date for the protocol as entered in PATS.
- **Patients Treated:** The total number of patients who have had at least one treatment course on this protocol.
- **Lead NSC:** The NSC + "," + NAME for the lead NSC for the protocol as entered in PATS.
- **Lead IND:** The lead IND number for the protocol as entered in PATS.
- **Cutoff Date:** The most recent date for which any data was used in compiling results. This date should reflect the latest date for which information is known. (YYYYMMDD).
- **Adverse Event Comments:** Any observations or conclusions regarding toxicities, adverse event and dose modification that may not be apparent from other information on this report**.**
- **Response Comments:** Observations or conclusions regarding response that may not be apparent from other information on this report.
- **Treatment Assignment Code:** A unique code identifying the type of treatment assigned for a clinical trial. The investigator specifies this information. The report includes a description of the code.
- **Subgroup Code**: Information on how patients in a protocol are uniformly grouped for analysis or treatment. These groupings are usually based on protocol stratification criteria, e.g., age, prior therapies, disease and/or node+/-. The report includes a description of the code.

Business Rules

Business rules do not determine this report's output.

Sample Report

A representation of this report is provided on the following page. This is a sample report for demonstration purposes only. Actual data in reports will vary.



Investigator Comments: Adverse Event and Response Report

Date : 03/23/2004

CALGB-39810 - A Phase II Trial of Trastuzumab (Herceptin) for Advanced Stage (IIIB, IV) , HER-2 Overexpressing, Non-Small Celll Lung Cancer

Phase: II **Lead Organization/PI:** Cancer and Leukemia Group B / Jeffrey A. Kern **Current Status, Status Date:** Closed to Accrual & Treatment, 04/03/2003

Lead IND#: 6667 **Lead NSC#:** 688097, Trastuzumab [Herceptin(R)] **Patients Treated:** 21 **Cutoff Date:** 09/30/2003

AE Comments: N/A

Response Comments: N/A

Treatment Assignment Code/Description: TA-1 / Trastuzumab [Herceptin(R)] 4 mg/kg IV over 90 Minutes Day 1, week 1
Trastuzumab [Herceptin(R)] 2 mg/kg IV over 30 Minutes on Day 1, weeks 2,3, and 4

Subgroup Code/Description: SG1 / Patients that have been previously treated

AE Comments: N/A

Response Comments: N/A

Treatment Assignment Code/Description: TA-1 / Trastuzumab [Herceptin(R)] 4 mg/kg IV over 90 Minutes Day 1, week 1
Trastuzumab [Herceptin(R)] 2 mg/kg IV over 30 Minutes on Day 1, weeks 2,3, and 4

Subgroup Code/Description: SG2 / Patients with no prior treatments

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Figure 77 – Sample Investigator Comments: Adverse Event and Response Report